(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 (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).

#### (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.—

''(1) EXTENSION.—Subject to paragraph (2), notwithstanding section 1175(b)(1)(A) of the Social Security Act (42 U.S.C. 1320d–4(b)(1)(A)) and section 162.900 of title 45, Code of Federal Regulations, a health care provider, health plan (other than a small health plan), or a health care clearinghouse shall not be considered to be in noncompliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, before October 16, 2003.

''(2) CONDITION.—Paragraph (1) shall apply to a person described in such paragraph only if, before October 16, 2002, the person submits to the Secretary of Health and Human Services a plan of how the person will come into compliance with the requirements described in such paragraph not later than October 16, 2003. Such plan shall be a summary of the following:

''(A) An analysis reflecting the extent to which, and the reasons why, the person is not in compliance.

''(B) A budget, schedule, work plan, and implementation strategy for achieving compliance.

''(C) Whether the person plans to use or might use a contractor or other vendor to assist the person in achieving compliance.

''(D) A timeframe for testing that begins not later than April 16, 2003.

''(3) ELECTRONIC SUBMISSION.—Plans described in paragraph (2) may be submitted electronically.

''(4) MODEL FORM.—Not later than March 31, 2002, the Secretary of Health and Human Services shall promulgate a model form that persons may use in drafting a plan described in paragraph (2). The promulgation of such form shall be made without regard to chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act').

''(5) ANALYSIS OF PLANS; REPORTS ON SOLUTIONS.—

''(A) ANALYSIS OF PLANS.—

''(i) FURNISHING OF PLANS.—Subject to subparagraph (D), the Secretary of Health and Human Services shall furnish the National Committee on Vital and Health Statistics with a sample of the plans submitted under paragraph (2) for analysis by such Committee.

''(ii) ANALYSIS.—The National Committee on Vital and Health Statistics shall analyze the sample of the plans furnished under clause (i).

''(B) REPORTS ON SOLUTIONS.—The National Committee on Vital and Health Statistics shall regularly publish, and widely disseminate to the public, reports containing effective solutions to compliance problems identified in the plans analyzed under subparagraph (A). Such reports shall not relate specifically to any one plan but shall be written for the purpose of assisting the maximum number of persons to come into compliance by addressing the most common or challenging problems encountered by persons submitting such plans.

''(C) CONSULTATION.—In carrying out this paragraph, the National Committee on Vital and Health Statistics shall consult with each organization—

''(i) described in section 1172(c)(3)(B) of the Social Security Act (42 U.S.C. 1320d–1(c)(3)(B)); or

''(ii) designated by the Secretary of Health and Human Services under section 162.910(a) of title 45, Code of Federal Regulations.

''(D) PROTECTION OF CONFIDENTIAL INFORMATION.—

''(i) IN GENERAL.—The Secretary of Health and Human Services shall ensure that any material provided under subparagraph (A) to the National Committee on Vital and Health Statistics or any organization described in subparagraph (C) is redacted so as to prevent the disclosure of any—

''(I) trade secrets;

''(II) commercial or financial information that is privileged or confidential; and

''(III) other information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

''(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to affect the application of section 552 of title 5, United States Code (commonly known as the 'Freedom of Information Act'), including the exceptions from disclosure provided under subsection (b) of such section.

''(6) ENFORCEMENT THROUGH EXCLUSION FROM PARTICIPATION IN MEDICARE.—

''(A) IN GENERAL.—In the case of a person described in paragraph (1) who fails to submit a plan in accordance with paragraph (2), and who is not in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or after October 16, 2002, the person may be excluded at the discretion of the Secretary of Health and Human Services from participation (including under part C or as a contractor under sections 1816, 1842, and 1893) [42 U.S.C. 1395h, 1395u, 1395ddd] in title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

''(B) PROCEDURE.—The provisions of section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to an exclusion under this paragraph in the same manner as such provisions apply with respect to an exclusion or proceeding under section 1128A(a) of such Act.

''(C) CONSTRUCTION.—The availability of an exclusion under this paragraph shall not be construed to affect the imposition of penalties under section 1176 of the Social Security Act (42 U.S.C. 1320d–5).

''(D) NONAPPLICABILITY TO COMPLYING PERSONS.—The exclusion under subparagraph (A) shall not apply to a person who—

''(i) submits a plan in accordance with paragraph (2); or

''(ii) who is in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or before October 16, 2002.

''(b) SPECIAL RULES.—

''(1) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

''(A) as modifying the October 16, 2003, deadline for a small health plan to comply with the requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations; or

''(B) as modifying—

''(i) the April 14, 2003, deadline for a health care provider, a health plan (other than a small health

plan), or a health care clearinghouse to comply with the requirements of subpart E of part 164 of title 45, Code of Federal Regulations; or

''(ii) the April 14, 2004, deadline for a small health plan to comply with the requirements of such subpart.

''(2) APPLICABILITY OF PRIVACY STANDARDS BEFORE COMPLIANCE DEADLINE FOR INFORMATION TRANSACTION STANDARDS.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, during the period that begins on April 14, 2003, and ends on October 16, 2003, a health care provider or, subject to subparagraph (B), a health care clearinghouse, that transmits any health information in electronic form in connection with a transaction described in subparagraph (C) shall comply with the requirements of subpart E of part 164 of title 45, Code of Federal Regulations, without regard to whether the transmission meets the standards required by part 162 of such title.

''(B) APPLICATION TO HEALTH CARE CLEARINGHOUSES.—For purposes of this paragraph, during the period described in subparagraph (A), an entity that processes or facilitates the processing of information in connection with a transaction described in subparagraph (C) and that otherwise would be treated as a health care clearinghouse shall be treated as a health care clearinghouse without regard to whether the processing or facilitation produces (or is required to produce) standard data elements or a standard transaction as required by part 162 of title 45, Code of Federal Regulations.

''(C) TRANSACTIONS DESCRIBED.—The transactions described in this subparagraph are the following:

''(i) A health care claims or equivalent encounter information transaction.

''(ii) A health care payment and remittance advice transaction.

''(iii) A coordination of benefits transaction.

''(iv) A health care claim status transaction.

''(v) An enrollment and disenrollment in a health plan transaction.

''(vi) An eligibility for a health plan transaction.

''(vii) A health plan premium payments transaction.

''(viii) A referral certification and authorization transaction.

''(c) DEFINITIONS.—In this section—

''(1) the terms 'health care provider', 'health plan', and 'health care clearinghouse' have the meaning given those terms in section 1171 of the Social Security Act (42 U.S.C. 1320d) and section 160.103 of title 45, Code of Federal Regulations;

''(2) the terms 'small health plan' and 'transaction' have the meaning given those terms in section 160.103 of title 45, Code of Federal Regulations; and

''(3) the terms 'health care claims or equivalent encounter information transaction', 'health care payment and remittance advice transaction', 'coordination of benefits transaction', 'health care claim status transaction', 'enrollment and disenrollment in a health plan transaction', 'eligibility for a health plan transaction', 'health plan premium payments transaction', and 'referral certification and authorization transaction' have the meanings given those terms in sections 162.1101, 162.1601, 162.1801, 162.1401, 162.1501, 162.1201, 162.1701, and 162.1301 of title 45, Code of Federal Regulations, respectively.''

## § 1320d–5. General penalty for failure to comply with requirements and standards

### (a) General penalty

#### (1) In general

Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part—

(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect—

(i) if the violation is corrected as described in subsection (b)(3)(A),[1] a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.

#### (2) Procedures

The provisions of section 1320a–7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1320a–7a of this title.

#### (3) Tiers of penalties described

For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

(D) the amount described in this subparagraph is $50,000 for each such violation, ex-

[1] So in original. Probably should be ''(b)(2)(A),''.