

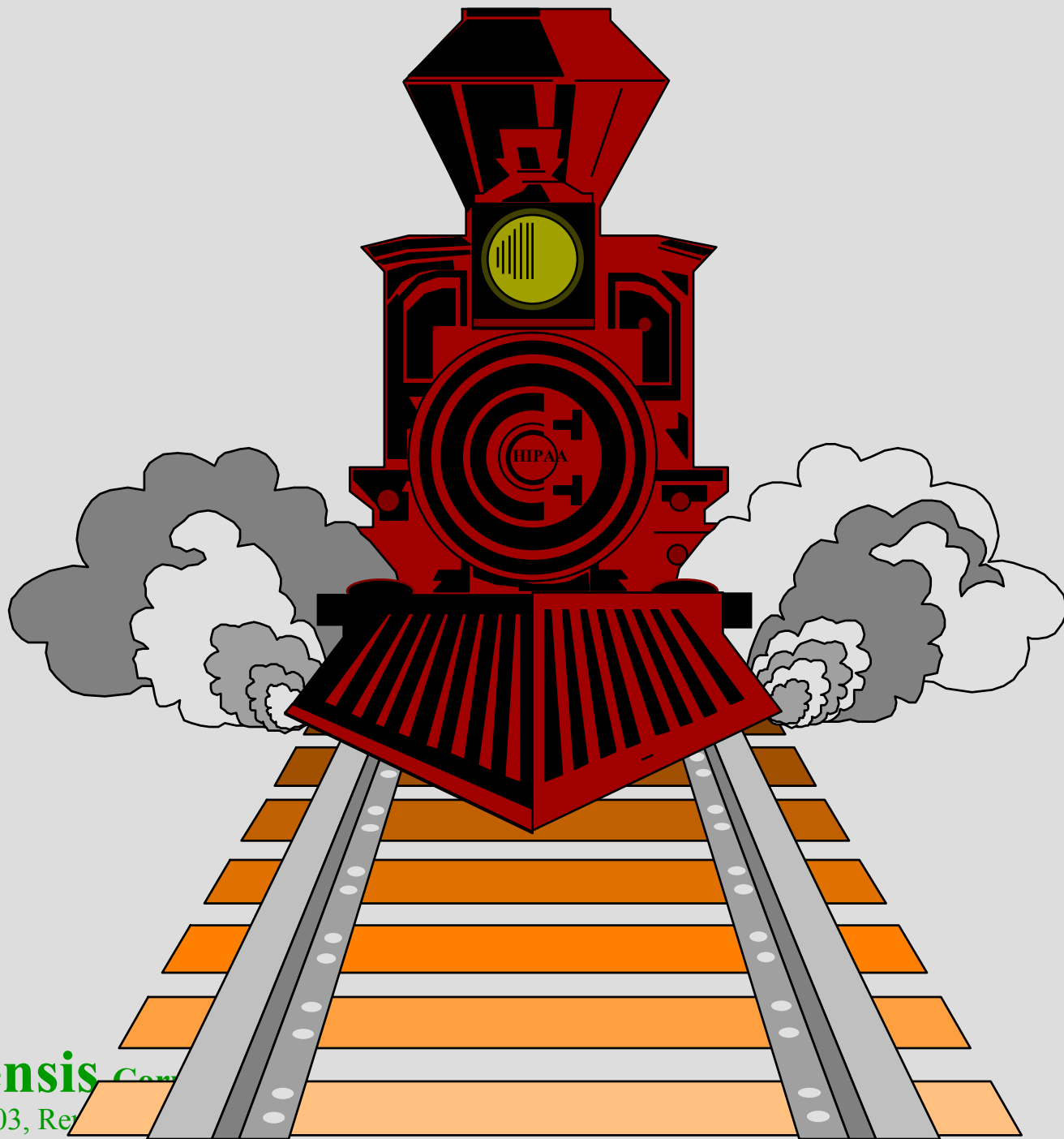
# HIPAA Transactions and Code Sets

## The Trains Will Keep Running

16 September 2003

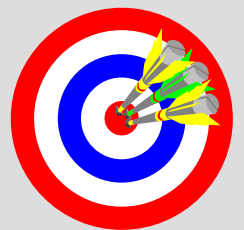
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*Intelligently Linking Information Systems*



# Covered Entities' Objectives

- Keep Electronic Data Interchanges (EDI) operational
  - Service customers
  - Maintain cash flows
- Transition gracefully to HIPAA compliant Transactions and Code Sets (TCS)
- Avoid HIPAA TCS Civil Money Penalties (CMP)



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- Consultant and Teacher -- Healthcare Interfaces and EDI
- Author, "Understanding HIPAA Communications"
- Member, Accredited Standards Committee X12 and its Insurance Subcommittee (X12N)
- Member, Health Level Seven (HL7)
- **Co-Chair, X12N HIPAA Implementation Work Group**
- Member, HL7 Attachments Special Interest Group (ASIG) and X12N Patient Information Work Group (TG2/WG9)
- Member, HL7 Imaging Integration Special Interest Group (IISIG) and DICOM Image Integration Group (WG20)
- Member, concluded HL7 Master Person Index Mediation Special Interest Group (MPISIG)
- **Commercial and Technology Arbitrator, American Arbitration Association**

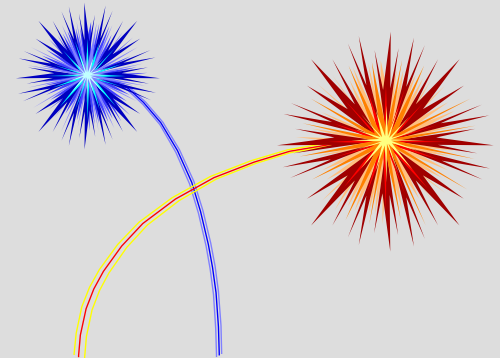


# “Train Wreck” Premise

- Starting on 16 October 2003, only two TCS tracks are possible:
  - HIPAA TCS-compliant EDI
  - Non-EDI (e.g., paper, voice phone)

# The Trains Will Keep Running

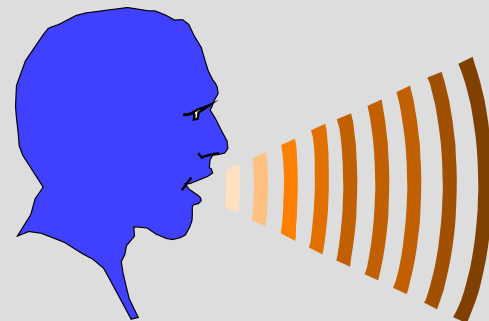
- Starting on 16 October 2003, only two TCS tracks are possible:
  - HIPAA TCS-compliant EDI
  - Non-EDI (e.g., paper, telephone)
- **There is a third track!**



# Third Track Characteristics

- Based on published and yet to be published Federal regulations, plus existing legislation
- Completely within each covered entity's internal management and control
- Requires crossing a few bridges along the way

***All aboardddd!***



# TCS Compliance Dates

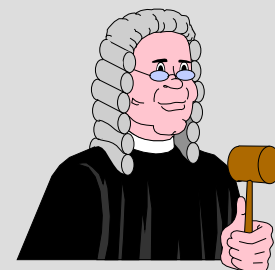
<u>HIPAA Transaction</u>	<u>Health Plan</u>	<u>Provider</u>	<u>Health Care Clearinghouse</u>	<u>Small Health Plan</u>
Claim	10/16/2002	10/16/2002	10/16/2002	10/16/2003
Eligibility	10/26/2002	10/16/2002	10/16/2002	10/16/2003
Referral	10/16/2002	10/16/2002	10/16/2002	10/16/2003
Claim Status	10/16/2002	10/16/2002	10/16/2002	10/16/2003
Enrollment	10/16/2002		10/16/2002	10/16/2003
Remittance	10/16/2002		10/16/2002	10/16/2003
Premium Pmt.	10/16/2002		10/16/2002	10/16/2003
COB	10/16/2002		10/16/2002	10/16/2003

**Note: These dates have not changed since their publication in the Federal Register on 17 August 2000!**



# TCS Compliance Status

- Health Plans, Providers, and Health Care Clearinghouses
  - Currently -- since 16 October 2002 -- non-compliant everywhere HIPAA standards are not in use for applicable electronic transactions
- Small Health Plans
  - Not in potential noncompliance until 16 October 2003



# But What About ASCA?

- The Administrative Simplification Compliance Act (ASCA, PL 107-105) explicitly does not change the compliance dates!
- ASCA does define conditions under which covered entities **“shall not be considered to be in noncompliance”**
- Consider this to be a delay in HIPAA TCS enforcement -- only.

# TCS Compliance Status with ASCA

- Health Plans, Providers, and Health Care Clearinghouses
  - Currently -- since 16 October 2002 -- non-complaint everywhere HIPAA standards are not in use for applicable electronic transactions
  - **Enforcement will not start until at least 16 October 2003**
- Small Health Plans
  - Not in potential noncompliance until 16 October 2003



# You've Got to Have a Plan

- Key ASCA enforcement-deferral condition is **“a plan of how the person will come into compliance”**
  - Non-compliance analysis
  - Budget, schedule, work plan, and implementation strategy
  - Plan for use of outside resources
  - Testing timeframe that begins no later than 16 April 2003

# Bridges to Cross

- 1 Most covered entities are already in [technical] noncompliance of HIPAA TCS
- 2 If you have an ASCA extension, you'd better have a compliance plan

# HHS' Enforcement Approach

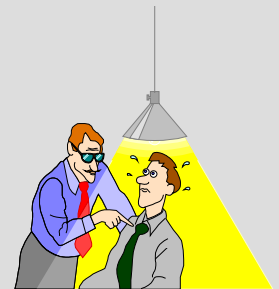
- Similar for TCS and Privacy
- Focus on voluntary compliance
- Provision of technical assistance
- Primarily complaint driven
- Progressive steps
  - Entity compliance demonstrations
  - Entity corrective action plans
  - Potential additional technical assistance

# Non-Penalty Situations

- Covered entity ...
  - did not know
  - has reasonable cause
  - does not demonstrate willful neglect
  - can comply in a certain time
  - civil money penalty (CMP) is excessive relative to compliance failure

# Non-Penalty Situations

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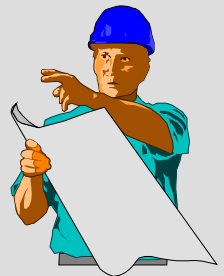


# Bridges to Cross

- 1 Most covered entities are already in [technical] noncompliance of HIPAA TCS
- 2 If you have an ASCA extension, you'd better have a compliance plan
- 3 Keep your compliance plan current
- 4 Ensure your TCS compliance project has been and continues to be appropriately resourced

# Bridges to Cross

- 5 Continue reasonably and diligently executing your TCS compliance plan
- 6 Go the extra step where rational
- 7 Document, document, document



# The Third Track

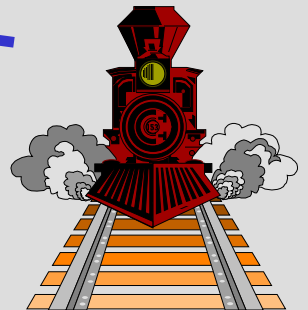
- *Where necessary*, continue business and transactions as usual
  - Parallel processing of current and HIPAA
  - Phased change-over from current to HIPAA
- Routinely update noncompliance status, with causes; maintain histories
- Routinely adjust real plan to achieve compliance; maintain histories
- Diligently execute real plan; log status

# The Third Track

- **Gracefully,  
steadily,  
become TCS compliant**

current transactions

HIPAA transactions



# One Last Item

- As of 8/15/2003, no HHS policies have been proposed, let alone finalized, for
  - Determining violations
  - Calculating CMPs*including any potential retroactive provisions*
- Establishing the above policies will employ
  - Notice of Proposed Rule Making (NPRM)  
[“no”, I don’t know any publication date]
  - Public comment period -- probably 60 days
  - Final rule

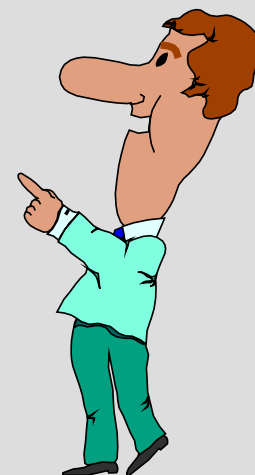
# HIPAA Transactions and Code Sets

## The Trains Will Keep Running

*Comments?*

*Questions?*

*Smart Remarks?*



# Appendix

## Applicable Acronyms

45 CFR 162.900

ASCA Sec. 2 (a)

HIPAA Modified Sec. 1176  
(*a.k.a.* 42 USC 1320d-5)

68 FR, 17 April 2003  
“Civil Money Penalties ...”  
portions of pages  
18896 and 18897

# Applicable Acronyms

ASCA	Administrative Simplification Compliance Act (PL 107-105)
CFR	Code of Federal Regulations
CMP	Civil Money Penalty
EDI	Electronic Data Interchange
FR	Federal Register
PL	Public Law
TCS	[HIPAA] Transactions and Code Sets
USC	United States Code



# 45 CFR 162.900

## **Sec. 162.900 Compliance dates of the initial implementation of the code sets and transaction standards.**

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of subparts I through N of this part no later than October 16, 2002.

(b) *Health plans.* A health plan must comply with the applicable requirements of subparts I through R of this part no later than one of the following dates:

(1) *Health plans other than small health plans* -- October 16, 2002.

(2) *Small health plans* -- October 16, 2003.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the applicable requirements of subparts I through R of this part no later than October 16, 2002.

# ASCA Sec. 2 (a)

## **Sec. 2. EXTENSION OF DEADLINE FOR COVERED ENTITIES SUBMITTING COMPLIANCE PLANS.**

(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.

# ASCA Sec. 2 (a)

(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 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, 2003, 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.

• • •

(6) ENFORCEMENT THROUGH EXCLUSION FROM PARTICIPATION IN MEDICARE.

• • •

# HIPAA Modified Sec. 1176

## **“GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS**

### **“SEC. 1176. (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 penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

“(2) PROCEDURES.-- The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

# HIPAA Modified Sec. 1176

## **“(b) LIMITATIONS.--**

“(1) OFFENSES OTHERWISE PUNISHABLE.-- A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

“(2) NONCOMPLIANCE NOT DISCOVERED.-- A penalty may not be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

“(3) FAILURES DUE TO REASONABLE CAUSE.--

“(A) IN GENERAL.-- Except as provided in subparagraph (B), a penalty may no be imposed subsection (a) if--

“(i) the failure to comply was due to reasonable cause and not to willful neglect; and

# HIPAA Modified Sec. 1176

“(ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

“(B) EXTENSION OF PERIOD.--

“(i) NO PENALTY.-- The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

“(ii) ASSISTANCE.-- If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

“(4) REDUCTION.-- In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

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## page 18896

### ***42 U.S.C. 1320d-5(a)***

Subsection (b) of section 1320d-5 sets out a number of substantive limitations on the Secretary's authority to impose CMPs. First, a CMP may not be imposed with respect to an act that "constitutes an offense punishable" under the criminal penalty provision. 42 U.S.C. 1320d-5(b)(1). Second, a CMP may not be imposed "if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision." 42 U.S.C. 1320d-5(b)(2). Third, a CMP may not be imposed if the failure to comply was due "to reasonable cause and not to willful neglect" and is corrected within a certain time. 42 U.S.C. 1320d-5(b)(3). Finally, a CMP may be reduced, if not waived entirely, "to the extent that the payment of such penalty would be excessive relative to the compliance failure involved." 42 U.S.C. 1320d-5(b)(4).

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## page 18897

“Enforcement activities will focus on obtaining voluntary compliance through technical assistance. The process will be primarily complaint driven and will consist of progressive steps that will provide opportunities to demonstrate compliance or submit a corrective action plan.” • • •

### ***HHS' Approach to the Enforcement Rule***

As noted above, HHS intends to issue an Enforcement Rule in furtherance of its implementation of 42 U.S.C. 1320d-5. The Enforcement Rule, in its entirety, will address a number of substantive issues relating to the imposition of CMPs under section 1320d-5, such as the Department's policies for determining violations and calculating CMPs. In addition, the Enforcement Rule will establish various procedures for the imposition of CMPs, including the procedures for providing notice and a hearing on the Secretary's determination to impose a CMP. This interim final rule implements this latter aspect of the Enforcement Rule.



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### ***Administrative Procedure Act***

We recognize that under the Administrative Procedure Act (“APA”) most of the above-described provisions of the Enforcement Rule must be promulgated through notice-and-comment rulemaking. We intend to do so. However, to allow covered entities and the public to be informed as soon as possible of procedural requirements that will apply as compliance proceeds, we are expediting the publication of these procedural rules in final form. These rules set out the procedures for provision by the agency of the statutorily required notice and hearing and procedures for issuing administrative subpoenas. Such provisions are exempted from the requirement for notice-and-comment rulemaking under the “rules of agency \* \* \* procedure, or practice” exemption at 5 U.S.C. 553(b)(3)(A). Even though notice-and-comment rulemaking is, therefore, not required with respect to the procedural rules adopted below, HHS is interested in input from the public, and thus is requesting public comment on them. We expect to augment these procedural rules with provisions that, while related to

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procedure, are substantive in nature. We anticipate including those provisions in the notice-and-comment rulemaking that we plan for the remainder of the Enforcement Rule. In any event, we plan to revise the procedural rule by the expiration date.

# HIPAA Transactions and Code Sets

## **The Trains Will Keep Running**

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