Centers for Medicare and Medicaid Services

ARE YOU A COVERED ENTITY? …

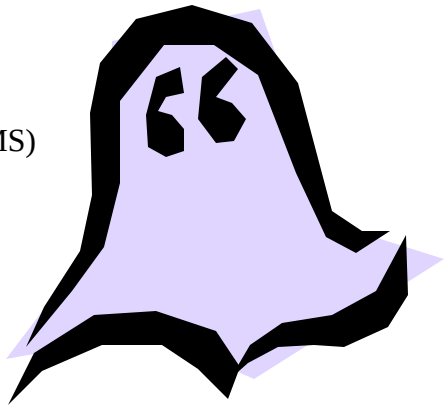
And When Does Rule 1 Apply?

ROAD MAPS TO HIPAA COMPLIANCE
VOLUME 2, MAP 1

August 24, 2001

ARE YOU A COVERED ENTITY?…

AND WHEN DOES RULE 1[1] APPLY?



INTRODUCTION

Volume 2 of the Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) series of white papers on topics important to the HIPAA implementation effort focuses on "HOW TO" solutions, practical guidelines to answering questions and resolving issues. This first paper in the new series explores the issues involved in determining the status of Covered Entities and the requirements for Covered Standard Transactions. It provides guidelines to assist you in drawing your HIPAA boundaries, determining when HIPAA compliance is mandatory, when is it voluntary, and when is it a matter of stating your case with the evidence to back it up.

The paper covers the following subjects:

- How to tell if you and your data trading partners are Covered Entities
- How to draw the boundary for your program, identifying the Covered Entities, covered standard transactions, and covered business cases within your domain and those that are beyond the pale
- Approaches for resolving the tough issues and answering the complex questions that require interpretation

The following summarizes the major Covered Entity questions addressed in this paper:

1. ***Are you a Covered Entity?***
2. ***Are you responsible for Covered Transactions?***
3. ***Does the Business Situation (Case) correspond to the intent of the Rules and/or Standards?***
4. ***Are you exempt from compliance but is there an opportunity to comply anyway to achieve consistency and efficiency in business processes?***

[1] The *Transactions and Code Sets Rule* is referred to as HIPAA "Rule 1" in this paper; *Privacy* is "Rule 2".

DISCLAIMER

Many aspects of HIPAA Rules 1 and 2 are being debated as organizations uncover atypical situations, not explicitly defined in the Rules. The information provided in this paper reflects the current state of the debate as of the date of publication. Each entity must make its own determination regarding its HIPAA compliance or exemption. We strongly urge you to seek your own legal counsel in these matters. We also encourage you to investigate the benefits of implementing HIPAA requirements even if your position is that you do not have to do so.

The complexity of State and local health care organizations can make it difficult to determine which components are Covered Entity health plans or providers, and where Rules 1 and 2 apply. Daily, State Medicaid agencies discover another anomaly in their business model as they attempt to fit into the HIPAA mold.

This paper explores some of the questions being asked by State and local entities and provides approaches to use in obtaining entity-specific answers.

Each organization must analyze its business processes, assess the impact of HIPAA, and determine the best course of action. If the organization meets an undisputed definition of Covered Entity in Rule 1, the need for compliance is clear.

However, for many other parties, and even for a Covered Entity, there are further requirements to explore before drawing the boundaries of HIPAA compliance.

Covered Entities

- Health Plan
- Health Care Clearinghouse
- Health Care Provider

- Each Covered Entity may hire a Business Associate to meet the requirements of compliance

Two Basic Conditions for HIPAA Compliance

1. You Meet the Definition of a Covered Entity.

2. You Exchange (send/receive) Information Meeting the Definition of Standard Transactions.

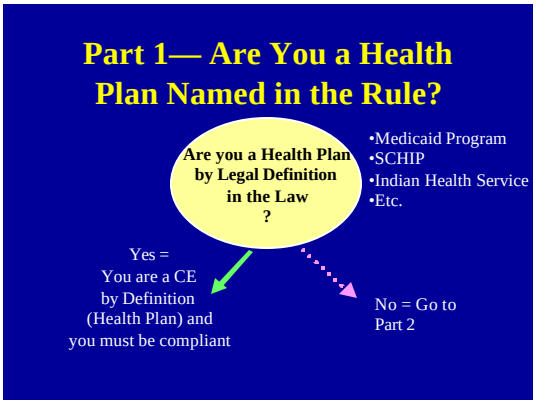
There are two official conditions for HIPAA compliance as shown on the left[2]. In addition, a corollary to the second condition has emerged as the health care industry strives to clarify issues and answer questions. The corollary condition is that the data exchange activity should meet the definition of a business case as intended in the Rule, the Implementation Guides, or in the U.S. Department of Health and Human Services (HHS) official clarifications or answers to questions. When both official conditions apply the transaction must be compliant. If one of the conditions is not met, or the business case calls for further analysis, then the Covered Entity may have sufficient grounds to comply or not.

[2] See DHHS title 45 CFR Parts 160 and 162, published in the Federal Register, Thursday, August 17, 2000; and Public Law 104-191, Title II, Subtitle F, Section 262 (Administrative Simplification) which adds Sections 1171 – 1179 to the Social Security Act, Title XI (42 U.S.C.), Part C (Administrative Simplification). Rule 2 amends Part 160 including additional definitions of inclusions and exclusions for "health plan".

The bottom line for a health plan meeting the definition of a Covered Entity is that there is no escape. The health plan must be ready to receive and respond to HIPAA-mandated Electronic Data Interchange (EDI) transactions in ASC standard formats as of D-Day. Providers have a choice of sending EDI, paper, fax, or automated voice response (AVR) as long as the health plan agrees to accept these media. In collaboration between health plans and providers, transactions can also be transmitted via Direct Data Entry (DDE) and the Web as long as the data content is compliant.

States and local publicly funded organizations need to develop a strategy for resolving the gray areas and determining how to handle anomalies. The following is a decision path to use in answering the first question: "Are You a Covered Entity?"[3]

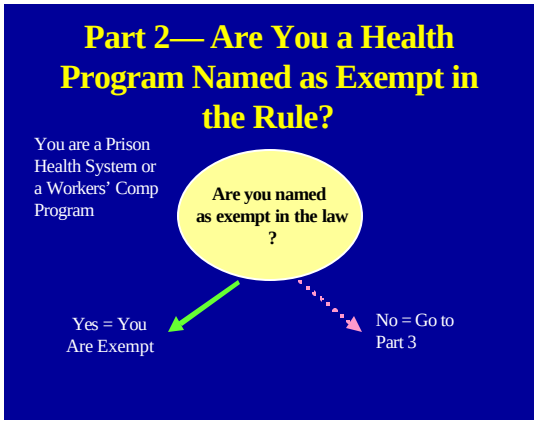
TAKE THE "ARE YOU A COVERED HEALTH PLAN" TEST

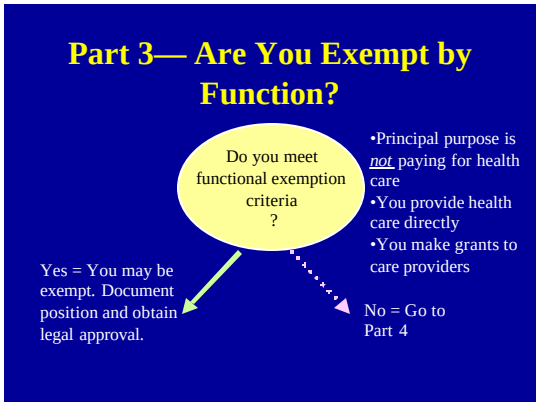


There are four parts to the Covered Entity test for Health Plans. The first one is easy—"Are you named in Rule 1 or 2"? The Medicaid program, the State Children's Insurance Program, Medicare, managed care organizations, Indian Health Service, and others are specifically identified in the legislation. But the Rules do not specify whether the Covered Entity health plan must be the designated single State agency for Medicaid or a Medical Assistance Division within the agency. It is important to decide at what level (high, low) the health plan will be named. At the highest level there are the benefits of single focus for transactions and privacy policy. At the lower levels there may be more flexibility and control over implementation decisions.

[3] The decision pathway illustrated in the Covered Entity tests is derived from a questionnaire developed by the State of Washington Department of Social and Health Services. Also see Federal Register, Volume 65, No. 160 (August 17, 2000 and Federal Register, Volume 65, No. 250 (December 28, 2000) for the full text of Rule 1. This includes the official U.S. DHHS Responses to public Comment, 45 CFR Parts 160 and 162, III. Analysis of, and Responses to, Public Comments on the Proposed Rule, B. *Definitions*, 4. Health Plan, pages 50319-50320. Rule 2 amends 160.103 with additional definitions of inclusions and exclusions for "health plan". See all the HHS FAQ web site for answers to questions on application of Rules: http://www.aspe.hhs.gov/admnsimp/

If your organization is not named in the Rule, proceed to Part 2 of the Test. Responses to Comments submitted for Rule 1 identify specific organizations or programs which are explicitly exempt, e.g., Workers' Compensation programs, Property and Casualty insurance plans, and prison health systems. The official Response refers to such organizations as "non-HIPAA" because they are not included in the definition of health plan in the law or the regulations. Such entities could choose to comply but are not required do so. In addition, Rule 2 amends section 160.103 of Rule 1 with more examples of included and excluded organizations.

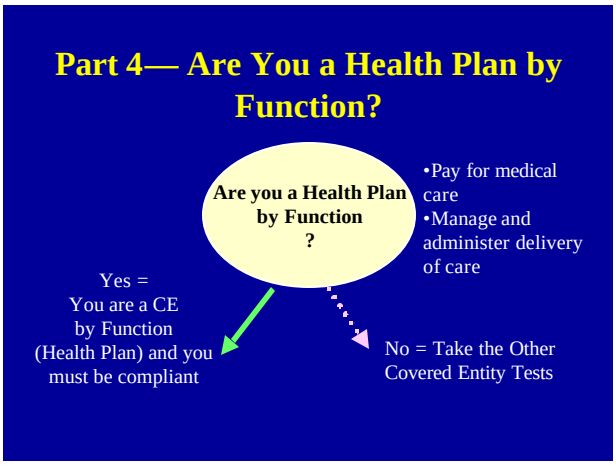




If you are not named as exempt in the Responses to Comments on Rule 1 (Part 2 of the Test) you may still be excluded *by business function*. Take Part 3 of the Test. Programs whose primary purpose is something *other than* the payment of health services but which may include a limited number of health care interventions or data processing may be exempt. Likewise, programs that provide care directly or which make grant payments to providers of care are exempt. (See Rule 2, section 160.103.) Health programs exempt under Part 3 of the Test can opt to implement HIPAA standards because of the benefits and efficiencies associated with standardization.

If you are not named as a Covered Health Plan in the Rule and are also not exempt as explicitly or implicitly stated in the Rule, then proceed to Part 4 of the Test. Part 4 is the critical test based on *functionality*[4]. This is the "Walks like a duck; talks like a duck…so it must be a duck" test. Basically, if you pay for health care, even though you are not named in the Rule, you *may be* a covered health plan. For many organizations, there is no doubt that the definition applies to them even though they are not named in the Rules.

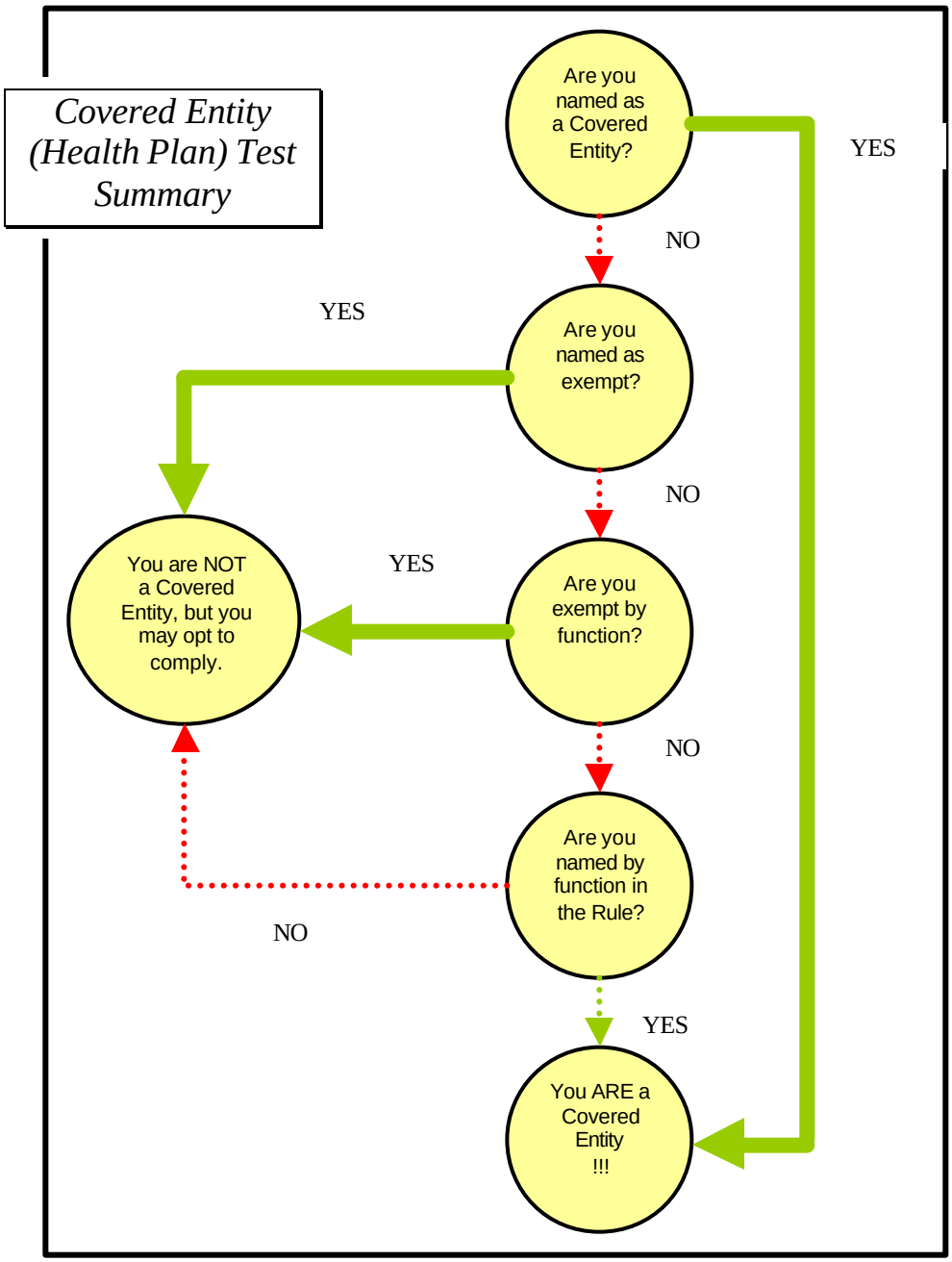
[4] 45 CFR Section 160.103 *Definitions: Health plan* (16) – Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(as)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).



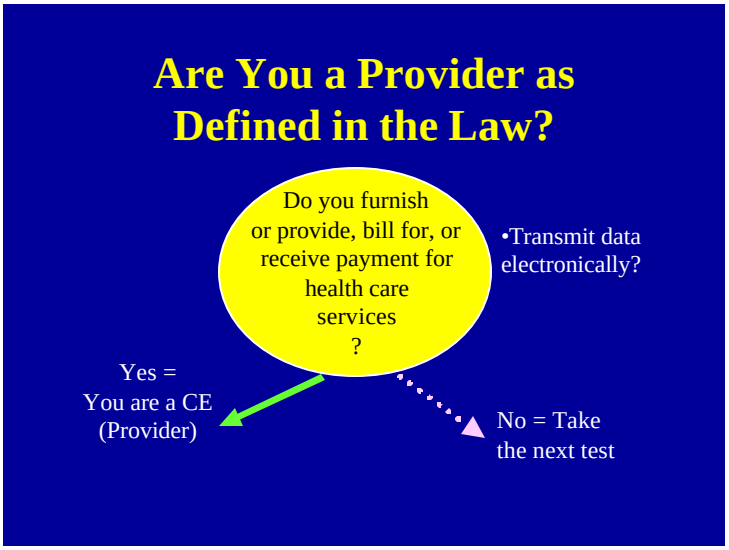
For example, many State Departments of Mental Health or County Departments of Health Services find that they fit the definition. In addition, the U.S. DHHS has clarified several of the borderline cases, i.e., Medicaid Waiver programs, no matter how they are administered, must comply with health plan requirements.

For other programs, more soul-searching and legal opinion are required to call the shot. Awareness of HIPAA has come late for many smaller programs which pay for medical care. These organizations do not typically think of themselves as "health plans". Later in the paper there is a list of examples of atypical programs – are they in or outside of the HIPAA circle?

The Covered Entity (Health Plan) Test Summary below puts the four parts of the Health Plan covered entity decision tree together. If you are a covered health plan, proceed to the " Do I Have to Comply?" tests to determine your requirements as a health plan regarding the implementation of HIPAA-mandated transactions. If you are not a health plan, take the next Covered Entity Tests.

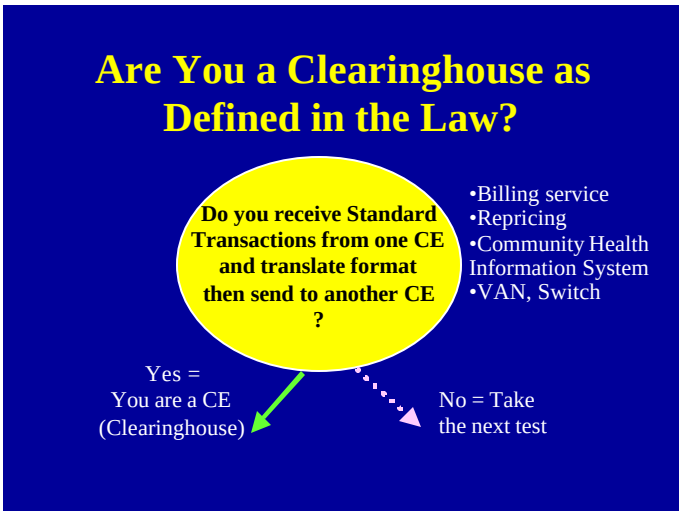

Covered Entity (Health Plan) Test Summary
Are you named as a Covered Entity?
YES
NO
Are you named as exempt?
YES
NO
You are NOT a Covered Entity, but you may opt to comply.
YES
Are you exempt by function?
NO
Are you named by function in the Rule?
NO
YES
You ARE a Covered Entity !!!

TAKE THE "ARE YOU ANOTHER COVERED ENTITY" TEST



Physicians, dentists, hospitals, laboratories, nursing homes, ambulance companies, pharmacies, and others are Covered Entities as defined in the Rule[5]. Some other types of providers, e.g., taxi cab companies, carpenters, home help personnel, are exempt. Waiver program providers typically include atypical providers. Waiver program health plans can choose to exempt taxi cab providers and others, but could also see if it is possible to integrate these atypical providers into a standardized electronic process, for example, using Direct Data Entry or web-based claims input.

Today, organizations not previously known or advertised as clearinghouses, now fit the definition of a clearinghouse defined in the final Rule 1[6]. A clearinghouse is any entity that is able to receive standard and non-standard transactions, convert them into the opposite, and forward the transaction to the receiver. Providers and health plans can become compliant by using a clearinghouse.



[5] See 45 CFR Part 160.103 of Rule 1 and as amended by Rule 2.
[6] See 45 CFR Part 160.103 of Rule 1 and as amended by Rule 2.

Since the clearinghouse is a Covered Entity named in the Rule, it must be fully compliant. Both providers and health plans (and even clearinghouses) can contract with a variety of business associates[7] to perform key business functions. Since the business associate is an extension of the Covered Entity, the Covered Entity must ensure that the business associates adhere to the Rules.

Because the Health Plan must be ready to receive and respond to standard EDI transactions, it has several related decisions to make:

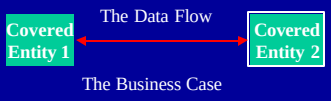
- Will it use a Clearinghouse to achieve compliance?
- Will it ask providers to use a single Clearinghouse?
- Will it license and install translator software to achieve compliance?
- Will it modify databases and programs to process the new standard data or will it try as far as possible to convert standard data to legacy data?
- Will it support dual processes to manage data obtained from compliant transactions and different data obtained from non-compliant transactions, e.g., paper, fax, or AVR?
- How will it deal with data not needed for processing but required when sending a compliant transaction?

[7] See 45 CFR Part 160.103 of Rule 1 and as amended by Rule 2.

YOU ARE READY FOR THE NEXT TEST—DO I HAVE TO COMPLY WITH RULE 1 (i.e., USE THE STANDARD TRANSACTIONS)?

Do I Have to Comply?

Take the HIPAA Business Activity Test:



Even if you are clearly a Covered Entity, the types of data exchange and related business contexts can still determine if the transaction must be compliant or not. As organizations probe deeper into the less obvious transactions and business processes, more questions are surfacing.

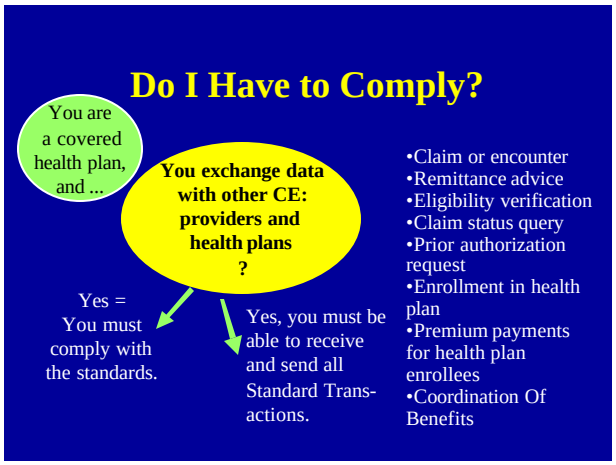
We suggest applying the "two conditions" test to clarify the certain requirements and uncover the gray areas which require judgment on the part of the organization.

Two Basic Conditions for HIPAA Compliance

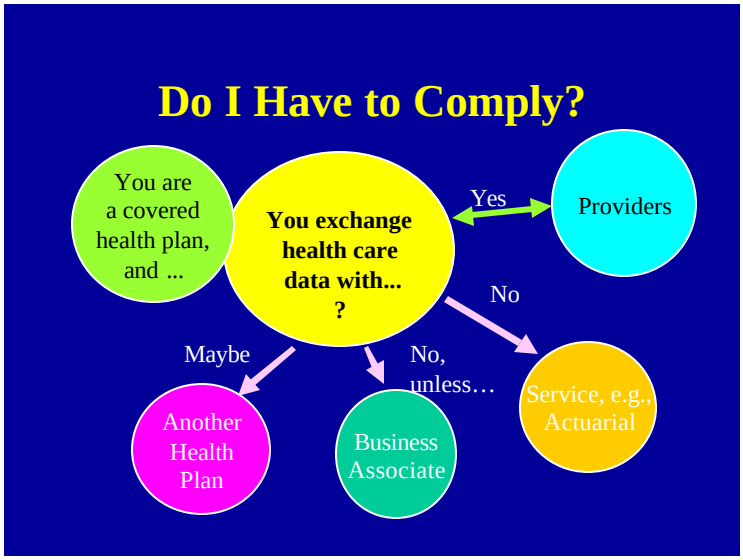
1. You Meet the Definition of a Covered Entity.
2. You Exchange (send/receive) Information Meeting the Definition of Standard Transactions.

   Corollary to 2: *The Data Exchange Activity Meets the Definition of a Business Case as Stated in the Rule, the Implementation Guides, or US DHHS Official Clarifications.*

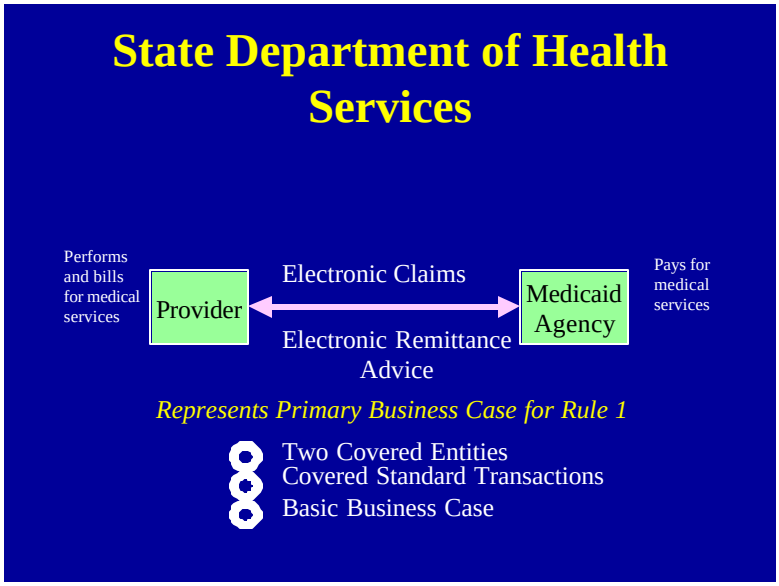
45 CFR Section 160.103 (Definitions) names eleven transactions, the first eight of which are mandated and therefore must be implemented by the deadline. First report of injury, health claims attachments, and other transactions are still under development. All health plans must be able to receive transactions sent to them by providers or health plans (claims, encounters, requests) and send covered transactions to providers and health plans (remittance advice, premium payment, enrollment, coordination of benefit claims, and responses). If providers want to transmit or receive any of these transactions electronically, they must use the HIPAA standard.



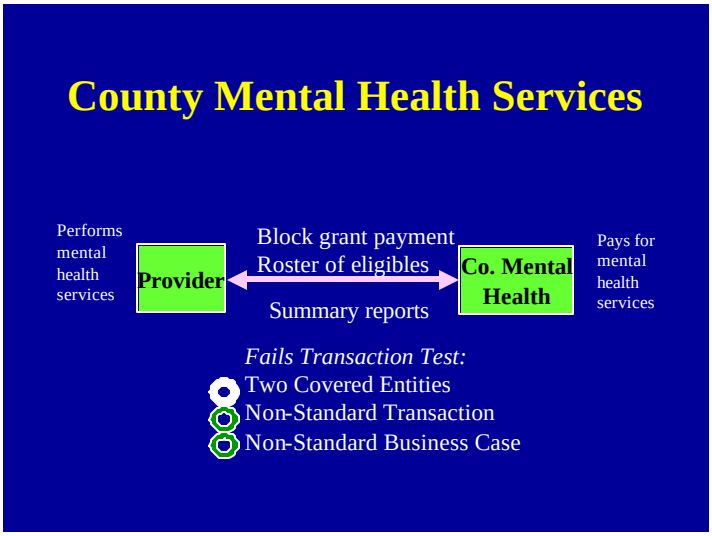
In the example below, a health plan exchanges data with different partners. If the data exchange meets the definition of a covered standard transaction, the transaction must comply with HIPAA requirements, i.e., when the provider sends an electronic claim and when the provider requests an electronic remittance advice, the payer must comply. If the health plan sends data to another health plan, the definition of the data sent and the business case are important to determining its HIPAA status. When the health plan sends data to a business associate, the transaction does not have to be compliant unless it meets the definition of a covered transaction. But the transaction may need to contain data content required for the creation of other HIPAA-compliant transactions. For example, enrollment data collected by an external enrollment broker must contain the codes required for the State to create an 834 enrollment transaction. Finally, if the health plan sends data to an actuarial contractor or an independent evaluator, the transaction does not need to be HIPAA compliant, but the health plan may choose to make it compliant in data content in order to maintain consistency in data.



The following examples show some of the combinations of Covered Entities, standard and non-standard transactions, and business cases requiring compliance or which are optional.

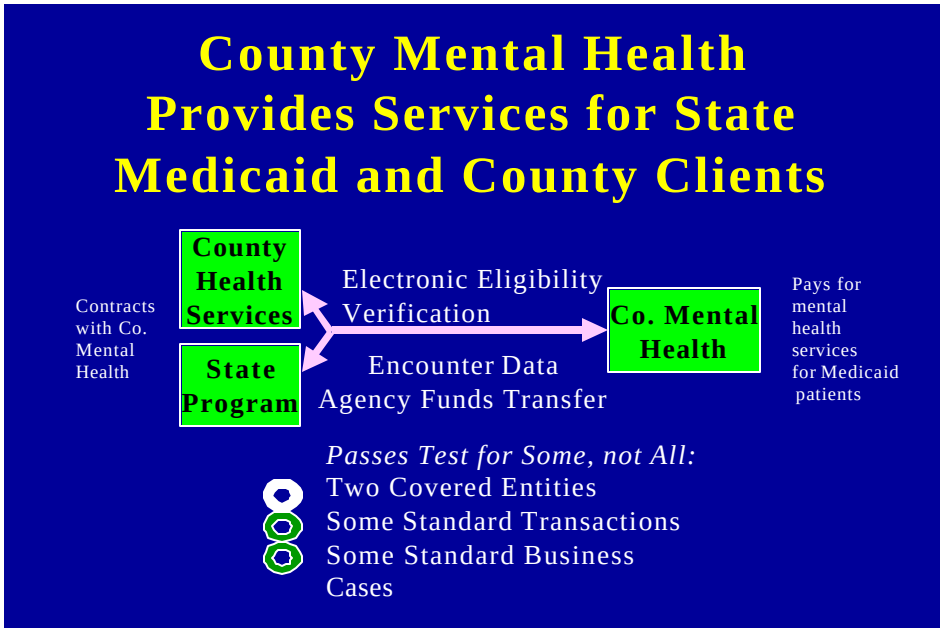


In the first example, there are two Covered Entities engaged in exchanging standard transactions in a business context identified in the Rule and Implementation Guides for these transactions. Compliance is required.

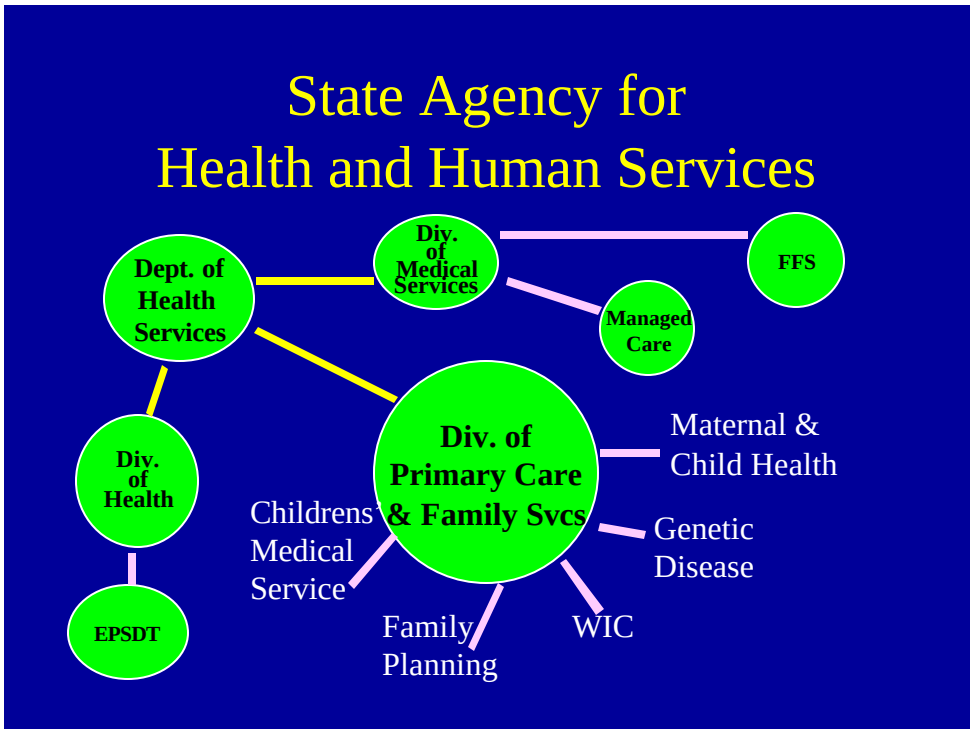


In the next example, there are two covered entities exchanging data, but the transactions do not meet the definition of any of the standard transactions named in 45 CFR Subsection 160.103. Compliance is not required.

In the next example, there is a mix of standard and non-standard transactions illustrating the need for interpretation, documentation, and legal advice on the decisions taken.



Organizations need to diagram their internal and external data exchanges and define which components are health plans, which fall under other health plans, and which are outside the HIPAA domain.



The following table presents a variety of programs that pay for health care and are therefore potential Covered Entities. The second column in the table shows some of the

ambiguities and gray areas that the organization needs to assess in order to render its opinion on HIPAA compliance.

POTENTIAL COVERED ENTITY	STATUS re RULE 1
1. Health program created through legislative appropriation and/or Tobacco Settlement dollars. Program covers small population and may pay providers through a voucher process, direct grants, or a payroll-like method.	a. Program pays the cost of medical care but may not see itself as a "health plan". b. Program providers may be exempt types under Rule 1. c. Program may be subject to Rule 1 (requires legal interpretation). d. Program may adopt HIPAA standards to improve its business processes. e. Program may contract with Medicaid agency to support HIPAA data exchange functions.
2. Crippled Children programs; Children's rehabilitative services. Programs contract with providers, enroll eligible children, pay claims, and approve prior authorization requests.	a. Appears to meet definition of Covered Entity: health plan b. Providers may want to submit HIPAA EDI transactions. c. Health plans must be able to send and receive HIPAA standard transactions. d. Programs may contract with clearinghouses, business associates, or Medicaid agency to process the standard transactions. e. Programs could remedy their systems to be HIPAA compliant.
3. Women, Infants, and Children program (WIC).	a. Deemed exempt because primary purpose is provision of nutritional and dietary services. b. May want to implement Rule 1 and 2 voluntarily to conform with community standards
4. Small health plans. Many potential health plans in Social Services or Public Health agencies may cover a small population and receive limited funding, qualifying them as small health plans with an extra year to implement.	a. Mix of regular and small health plans has an impact on scheduling and planning. The small health plan has an extra year to implement HIPAA requirements.
5. Fill in the blanks. Organizations are invited to add their atypical (potential) health plan to this list.	Document

The next chart lists a number of situations where two Covered Entities exchange a standard data. The right-hand column presents requirements where the situation is clear or options where there are alternative positions.

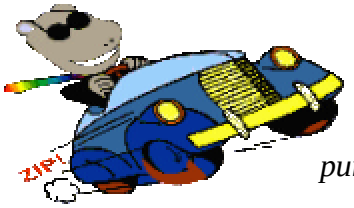
DOES RULE 1 APPLY TO ME?	
TRANSACTION/ SITUATION	**ASSUMPTIONS/ CONDITIONS[8]**
1. Provider sends fax request for prior authorization to the health plan.	a. Health plan is capable of accepting an electronic prior authorization request (278). b. Health plan does not require electronic 278. c. Health plan responds via telephone, fax, or mail.
2. Provider telephones health plan to request eligibility verification.	a. Health plan is capable of accepting an electronic eligibility verification request (270). b. Health plan accepts telephone inquiries. c. Health plan does not require the provider to use 270.
3. Health plan sends paper Remittance Advice (RA) to provider.	a. Health plan is capable of sending an electronic RA (ERA). b. Provider does not request an ERA. c. Health plan chooses to send paper RA.
4. Provider sends an electronic eligibility verification request (270).	a. Health plan returns a 271 response. b. Health plan may also respond via telephone or fax under certain conditions, e.g., network problems.
5. Provider sends an electronic claims status request (276).	a. Health plan returns a 277 response. b. Health plan may also respond via telephone or fax under certain conditions, e.g., network problems.
6. Pharmacy provider sends an NCPDP 5.1 transaction. Does the pharmacy provider also send a separate 270 for eligibility verification?	a. No. Eligibility verification is included in the response to the 5.1 transaction.
7. Provider sends in a real-time 270 and expects a real-time response.	a. Health plan has implemented real-time 270 processing. b. Health plan can also accept batch 270s.
8. Health plan receives TANF enrollment transactions from the agency or department responsible for determining eligibility.	a. This data exchange is considered exempt by DHHS. The eligibility determining agency is neither a health plan nor a business associate. b. Health plan needs to verify that the data received from the TANF transaction contains codes needed by the health plan to meet the Subscriber requirements of the standard transactions.
9. Provider wants to send an electronic prior authorization request (278). But the 278 lacks the clinical information the health plan requires in order	a. Health plan must be able to accept the 278 but may not be able to process it due to lack of clinical information needed to make the decision

[8] *Assumptions and interpretations are based on Industry positions, the final Rule 1, Department Responses to public Comment attached to Rule 1, and HHS FAQ publications. As presented above, these statements are NOT official rulings by any DSMO or HHS. Each Covered Entity must come to its own conclusions. We recommend documenting the conclusions and obtaining in-house legal counsel.*

DOES RULE 1 APPLY TO ME?	
TRANSACTION/ SITUATION	**ASSUMPTIONS/ CONDITIONS[8]**
to approve or disapprove a request.	to approve or deny. b. Health plan could respond with a 278 to deny the request. c. NMEH sub-workgroup on PA may develop an attachment which could be approved as a standard (future). d. Industry could propose a NEW standard transaction for PA requests requiring clinical data (future). e. Health plan and provider can agree to use a paper or electronic attachment in addition to the 278. f. Health plan conducts a risk assessment regarding impact of not using the 278 for prior authorization.
10. The State's enrollment broker contractor (business associate) sends enrollment information to the State.	a. This information does not have to be transmitted in a standard enrollment format (834). b. The information must contain any data content that the enrollment business associate collects and the health plan uses to transmit enrollment and disenrollment transactions (834s) to the MCOs.
11. Health plan sends enrollment/disenrollment transactions (834) to the MCO. In some States, the Medicaid agency and the MCOs have agreed (currently) to provide demographic and other detailed data not included in the 834 standard.	a. Enrollment transaction must meet the requirements of the standard. b. Health plan is only obligated to send the 834. c. MCO must be able to receive the 834. d. State may send additional data to the MCOs, but not as part of the standard 834. The additional data would be a different data set, not an Enrollment transaction. It is transmitted separately from the 834.
12. Provider sends electronic claims (837). Health plan responds with 997 acknowledgment transaction and/or an unsolicited 277 request for additional information.	a. The acknowledgment transaction and the unsolicited 277 are optional and are not a standard required by Rule 1.
13. Health plan requires attachments before payment can be made for certain claims.	a. There are no standards for attachments named in the regulations. Any format is permitted today. b. Several attachment protocols are under development and DSMOs will be petitioned to accept them (future).
14. Health plan requires MCOs to submit encounter data periodically as part of the contractual agreement.	a. Some health plans maintain that encounter data does not meet the business definition of the 837 and therefore does not need to be compliant. b. Some health plans may require the MCO to submit 837 transactions. c. Some health plans may require the MCO to submit HIPAA-compliant DATA CONTENT (code sets) only, using a non-standard transaction.

DOES RULE 1 APPLY TO ME?	
TRANSACTION/ SITUATION	**ASSUMPTIONS/ CONDITIONS[8]**
15. Health plan is a department within a Social Services agency and it only manages and pays for waiver programs. Total annual expenditures of $5 million or less qualifies this health plan as "small". Health plan receives and pays for claims. Both transactions are currently paper. Some big providers may want to send an electronic 837 claim and may want to receive an ERA.	a. A small health plan must have the capability of sending and receiving all standard transactions by October 16, 2003 (one more year to implement). b. Some providers may not be able to or want to submit 837s or receive 835s. c. Health plan needs to assess risk of not meeting all standard requirements. d. Health plan may be able to meet all requirements through a contract with a Clearinghouse, a business associate, or another health plan, e.g., contract with Medicaid agency to use MMIS for waiver claims.

The questions posed above represent some but not all of the questions State and local health agencies face. Every day, new atypical situations are identified and the health care industry tries to come up with reasonable answers. However, these answers are not official. It is possible that not all questions raised by the industry and sent to HHS can be officially answered by the Department before the implementation deadline for Rule 1. Organizations must complete their analysis of the impact of HIPAA, determine the actions they will take, and move forward with implementation despite the number of unanswered questions. Due diligence is an important consideration in documenting the actions taken. Legal counsel needs to be consulted regarding the final decisions made and the documentation collected to support the organization's decision.



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