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The HIPAA Transactions and Code Sets Rule: The Case for Flexibility in Data Content Standards

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The events of October 16, 2003 will shape whether Administrative Simplification under HIPAA will be regarded as a failure or as the success it could be.

On that date, covered entities will be required to comply with the Standards for Electronic Transactions and Code Sets Regulation (''TCSR'' or ''the Regulation''),[1] promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (''HIPAA'').[2] If there are significant disruptions in the claims payment process or a large-scale reversion to paper claims, at least in the short run, the effort will be deemed to have failed. If large-scale disruptions are avoided, the industry and the government will be seen as having made considerable progress toward standardization in the processing of health claims and toward the myriad of benefits that are expected to result.

There is widespread agreement that many providers and payers are not ready to transition completely from the old way of processing electronic claims to the new. Working against a smooth transition, in addition to the enormous complexity of the task and the compressed timeframes involved, is an unnecessarily rigid interpretation of the rules regarding standardized data content. The Department of Health and Human Services (HHS) can help avoid significant disruptions throughout the industry by issuing guidance clarifying that the HIPAA standards provide some flexibility as to the data content required in standard transactions.

[1] 45 C.F.R. pts. 160 and 162.

[2] Public Law 104-191, 110 Stat. 2021 (1996).

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I. Background

By requiring ''HIPAA Administrative Simplification,'' including standardization in electronic health transactions, Congress intended to promote the fast and cost-effective exchange of medical, billing, and other information; to reduce substantially handling and processing time; to eliminate the risk of lost paper documents; and to eliminate the inefficiencies of handling paper

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documents.[3] The intended results: a reduction in administrative burdens, lower operating costs, and an improvement in overall data quality.[4]

To these ends, HHS adopted the TCSR in August 2000. The TCSR includes industry-adopted standards and implementation specifications governing the electronic transfer of health information. It applies to ''covered entities,'' that is, all health plans and all health care clearinghouses, as well as to all health care providers who engage in covered electronic transactions. The eight ''standard transactions'' under the TCSR are:

- Health care claims or equivalent encounter information
- Eligibility for a health plan
- Referral certification and authorization
- Health claim status
- Enrollment and disenrollment in a health plan
- Health care payment and remittance advice
- Health plan premium payments
- Coordination of benefits

The Regulation also adopted procedures for maintaining, modifying and adding to the standards.[5] HHS adopted a revised set of standards in February 2003, before the first set of standards had been implemented.

Already, the Regulation has led to a considerable degree of standardization in the processing of electronic health claims. Payers and providers across the industry have converted or are preparing to convert from using hundreds of electronic formats to just one. Millions of claims are already being processed every week in the new HIPAA standard format. The number of code sets in use is being dramatically reduced. The maximum data set has limited and standardized the data content that can be required by payers and sent by providers. Testing the new electronic transactions, although far from complete, is on-going across the industry. This progress will be put at risk if there are significant disruptions in claim processing and payment, fueled by inappropriately rigid views of the data that is required to be in each claim.

II. The Role of HHS

HHS has already taken an important first step to facilitate implementation of the new transaction standards. On July 24, 2003, the Centers for Medicare & Medicaid Services (''CMS'') sponsored an ''Open Door Forum'' teleconference, in which approximately 1500 parties participated. As part of the forum, CMS released enforcement guidance that recognized many covered entities will not be fully transitioned to the new standards. The guidance makes clear that claims payment should not be disrupted and covered entities may employ contingencies (including the continued transmission of non-HIPAA standard formats) in order to ensure the smooth flow of payments *provided* they have made reasonable and diligent efforts to become compliant and to facilitate the compliance of their trading partners. [6] Although these efforts by HHS represent important steps in averting an implementation crisis, they fail to address the potentially chronic and debilitating problem of an unnecessarily narrow interpretation of the requirements regarding data content.

Standard electronic health transactions involve three distinct parts: format, code sets, and data content. To analogize to a paper claim, one can think of format as the envelope in which the claim is sent and code sets as the language in which the claim is written. Data content is the actual information in the claim. Congress mandated that ''any standard adopted under this part [Administrative Simplification] shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.''[7] This mandate can and should be achieved through an interpretation of the standard that includes flexibility in data content requirements. This flexibility will assist the health care industry in migrating to EDI in a manner consistent with the ultimate goal of Administrative Simplification: the control of health care costs through increased efficiency and reduced administrative expenses.

Under its existing authority, HHS could promote a more successful transition by clarifying that: (1) trading partners have flexibility in using a subset of the data content defined by the maximum data set; and (2) claims that contain errors or lack certain data elements may nonetheless be considered standard claims and

[3] 63 Fed. Reg. 25272 (May 7, 1998). The need for migration to and standardization in electronic data interchange (EDI) is beyond debate. HHS has estimated that approximately 400 formats for electronic health claims have been used in the United States. 65 Fed. Reg. 50312 (Aug. 17, 2000). Regarding the health care remittance standard established under the Regulation, HHS stated that in 1996 fewer than 16 percent of Medicare Part B providers were able to receive this standard. 63 Fed. Reg. at 25302. Similarly, HHS observed that ''very few'' providers currently use the electronic format for health care claim status. *See id*. Regarding eligibility for health plan determinations, health care providers secure most eligibility determinations through a combination of telephone calls, proprietary point of sale terminals, or through the use of proprietary electronic formats that vary between health plans. *See id*. at 25304. Likewise, regarding the referral certification and authorization standard, although prior approvals are standard procedure for most hospitals, physicians, and other providers, most approvals are secured through telephone calls, paper forms, or proprietary electronic formats that differ between plans, resulting in an untimely and inefficient process requiring redundant software, hardware, and human resources. *See id*. Regarding code sets, HHS has similarly noted that as health plans can differ regarding the codes that they are willing to accept, many providers use different coding guidelines with different health plans. Although HHS is unable to quantify the number of codes, it has opined that there is ''widespread'' use of other codes. *See id*. at 25301.

[4] 65 Fed. Reg. at 50312.

[5] 45 C.F.R. § 162.910

[6] The forum and the guidance clarified planned enforcement practices and steps that covered entities should take to demonstrate ''good faith'' efforts to comply with the TCSR. Among the key clarifications were the following: (i) evidence of good faith efforts to comply will include increased attempts to test with trading partners and outreach efforts by health plans to assist submitting parties with compliance; (ii) enforcement will be complaint-driven and good faith efforts to comply with the Regulation will be a part of any CMS review; and (iii) concerns about enforcement should not stand in the way of payers taking steps to pay claims. The guidance, however, addresses enforcement action after a covered entity has violated the Regulation. It does not address the essential question of what, in the first instance, is a standard or compliant claim. The ''Guidance on Compliance with HIPAA Transactions and Code Sets After the October 16, 2003, Implementation Deadline'' is available at www.cms.gov/HIPAA/HIPAA2.

[7] 42 U.S.C. § 1320d-1(b).

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may be processed and adjudicated by payers. In essence, a trading partner, or, when applicable, trading partners, would be permitted to engage in—that is, transmit, receive, and process—standard transactions that lack certain data elements, whenever such data elements are determined by the appropriate trading partner(s) to be not relevant to the transaction, or not reasonably necessary to process the transaction. This would hold true for the omission of any data element—including those that would otherwise be ''required'' data elements to a transaction.

III. Understanding the Regulation: Standard Transactions and Data Content Standards

An understanding of the function and importance of the data content standards requires, as a preliminary matter, an understanding of the scope and the structure of the Regulation.

A. The Standard Transactions Requirement

Under the HIPAA statute, electronic health care transactions must be conducted according to the HIPAA standard. Health plans may not refuse to conduct a transaction as a standard transaction. Moreover, plans may not delay the processing of, or adversely affect or attempt to adversely affect a person for submitting a standard transaction, or the transaction itself, on the grounds that the transaction is a standard transaction.[8] By contrast, providers are not required to engage in electronic transactions.[9] Providers may return to paper transactions in order to avoid the burdens of HIPAA Administrative Simplification. The industry is not equipped to process a massive influx of paper transactions. Therefore, the threat of providers moving to paper is of significant concern to payers.

Violations of the TCSR are subject to civil monetary penalties of no more than $100 per person per violation, and no more than $25,000 per person per violation of an identical requirement or prohibition in any calendar year.[10] In addition, criminal penalties are available under HIPAA, although the applicability of criminal penalties in the context of a violation of the TCSR has engendered discussion and debate within the health care industry and merits clarification by U.S. Department of Justice.[11]

B. Standard Data Content

As stated earlier, each electronic transaction includes format, code sets and data content. For each standard transaction, HHS has defined standard data content through the corresponding Implementation Guide (''IG'').[12] Standardization of data content includes an enumeration of data elements that may be in a transaction, a definition of the information to be contained in a particular data element— e.g. distinguishing between a home address and an email address— as well as the format of the information and any code sets or values that can be used to express the information.[13]

In comparison to format or code sets, data content has proven more difficult to standardize in health care transactions. This is due, in part, to the wide variety of health experiences that must be addressed in health care transactions. Equally important, the qualitative and subjective character of the information to be conveyed lends itself to ambiguity and multiple interpretations. Furthermore, data content is subject to human participation in a way that format and code sets are not. The difference between implementing format and code sets and implementing data content can be compared to following grammar rules verses writing an essay: the former are more readily standardized than the latter.

C. The Maximum Defined Data Set Principle

As a means of standardizing data content, HHS defined and adopted the principle of the ''maximum defined data set.'' The transaction standards divide data content into two categories: (1) ''required'' data elements; and (2) ''situational'' data elements that may or must be included only in specified circumstances. A maximum defined data set consists of all the required data elements for a particular standard based on a specific implementation specification.''[14] The purpose of this principle, HHS notes, is ''to set a ceiling on the nature and number of data elements inherent to each standard transaction and to ensure that health plans did not reject a transaction because it contained information they did not want.''[15]

While rejecting the notion of a minimum data set, HHS noted that the Implementation Guides were to result in a submission of the ''*minimum amount* of data elements *necessary* to process the transaction.''[16] HHS describes this ''minimum amount'' as ''the required data elements and the relevant situational data elements.''[17] The language of the preamble suggests that HHS discourages supplying possible but unnecessary situational data elements.[18] This is consistent with data content flexibility provided in the Implementation Guides.

Trading partners are granted flexibility to customize and define data content requirements within the param-

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[8] 42 U.S.C. § 1320d-4(a)(1). However, a health plan is not necessarily required to pay a claim simply because it is submitted in a ''HIPAA-compliant'' format. As noted by HHS, while the health plan must accept the HIPAA-compliant claim, if other business reasons exist for denying it (e.g., the claim is not for a service covered by the health plan), the claim may be denied. 65 Fed. Reg. at 50315.

[9] *See* 65 Fed. Reg. at 50314.

[10] 42 U.S.C. § 1320d-5(a)(1).

[11] *See* id. § 1320d-6.

[12] ''Data content'' is defined as ''all the data elements and code sets inherent to a transaction, and not related to the format of a transaction. Data elements that are related to the format are not data content.'' 45 C.F.R. § 162.103. ''Format'' means ''those data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a transaction.'' *See id*.

[13] Two types of code sets are used for data elements in the transaction standards: (1) large coding and classification systems for medical data elements; and (2) smaller sets of data elements for such things as type of facility, type of units, and a specified state within address fields. 63 Fed. Reg. at 25275. The large code sets include coding systems for the manifestations and causes of diseases, injuries, impairments, and other health related problems, and actions taken to prevent, diagnose, treat, or manage such diseases, injuries, and impairments, as well as any substances, equipment, supplies, or other items to perform these actions. Id. at 25280. The smaller sets of codes relate to other data elements such as type of facility, and type of unit.

[14] Id. § 162.103.

[15] 65 Fed. Reg. at 50322.

[16] *See id*. (emphasis added).

[17] *See id*.

[18] *See id*.

eters established by the TCSR's maximum defined data set. Read in light of the congressional mandate that the HIPAA standards reduce costs and facilitate electronic transactions, it should be clear that the TCSR was not meant to require all claims to carry full data content, regardless of what a payer needs or wants. To do so would increase sharply the cost of conducting transactions and would be inconsistent with congressional intent.[19] Furthermore, HHS explicitly rejected the notion of the Implementation Guides serving as minimum data sets in favor of the maximum data set concept.

Through the maximum data set concept, the law gives covered entities discretion to decide which elements of the data set they will require based on the information needed to process a claim.[20] HHS has already acknowledged as much in its HIPAA Information Series stating that ''HIPAA implementation guides provide health plans some flexibility to determine what data content to require within a specific format.''[21] HHS has explicitly applied this flexibility to the situational data elements. Under the congressional mandate, this flexibility should logically extend to those data elements designated by HHS as ''required'' as well. Indeed, as trading partners are discovering through the testing process, there are many instances where data elements—including those adopted by HHS as ''required''—are not *necessary* for the processing of the transaction. In fact, in many cases, the *elimination* of such data elements from a transaction would enhance the efficient administration of the standard transaction, while their inclusion only hinders or stops the transaction.

D. The Role of Translators

It was anticipated that ''HIPAA translators''—technology solutions that could translate old formats into new—would be a critical part of the migration to standard electronic transactions. The preamble to the proposed TCSR notes that each of the transactions were ''designed, and the technical review process assures, that it will be compatible with the commercial, off-the-shelf translator programs that are widely available in the United States.''[22] The preamble further notes that ''translators significantly reduce the cost and complexity of achieving and maintaining compliance with all ASC X12 standards. Universal communication with all parties is thus assured.''[23]

Unfortunately, hopes for the compatibility between the standard transactions and commercial translator programs, and the utility of translators in assuring communication between parties, is at odds with the experience of many in the health care industry. The testing process is showing increasingly that the less sophisticated translator programs typically do not incorporate the flexibility regarding data content standards that will be necessary to achieve a successful EDI migration and otherwise to comply with the HIPAA statute's mandate for lower costs and raised data quality. In some cases, the HIPAA translators have been programmed with such strict HIPAA editing functions that small data errors completely irrelevant to processing and paying a claim could result in large-scale claim rejections.[24]

IV. Data Content Analysis: Recognizing the Discretion of Trading Partners

The authority to define data content in a standard transactions, be they defined as ''required'' or ''situational'' by the Implementation Guides, should rest with the trading partners. For health care claims, it is the payer that will often determine which data elements are reasonably necessary to process claims, as it is the payer who is responsible for adjudicating whether or not the services rendered are payable under the benefits plan. A ''required'' data element should be considered one that a payer may always require if it is reasonably necessary to process a claim. A ''situational'' element of content is one that may be required only when the conditions specified in the Implementation Guides are met. Submitters should not be required to send more data elements than the payer needs. For other transactions (e.g., enrollment and disenrollment; referral and authorization) where submitter and receiver obligations are placed on different parties, the responsibility to specify whether a smaller subset of data elements are ''required'' (i.e., necessary) for the transaction may fall on different parties.

Support for finding flexibility in data content can be found in the ASC X12N Implementation Guides, which expressly recognize the authority of trading partners to identify a subset of elements the payer wants to receive. For example, Health Care Claim (837) IG provides that:

> [I]t is permissible for trading partners to specify a subset of an implementation guide as data they are able to *process* (sic) or act upon most efficiently. A provider who sends the payer [data elements that the payer does not need] has just wasted their resources and the resources of the payer. Thus, it behooves trading partners to be clear about the specific data within the 837

[19] Moreover, even in cases where the maximum data set is necessary and required, errors will continue to occur — Administrative Simplification can reduce, but not eliminate, errors. For this reason, HHS should clarify that the Regulation grants payers the necessary flexibility to accept adjudicable claims even with missing or invalid data content elements. For further discussion of this issue, *see* Richard D. Marks, ''Surviving Standard Transactions: A HIPAA Roadmap,'' 12 HLR 901, 6/5/03.

[20] Under this concept, a payer may choose to accept a subset of the maximum data set based on the information needed to process a claim. A payer may not, however, require more than the maximum defined data set for a transaction or reject a transaction because it contains more elements than the payer needs; the payer must be capable of accepting the maximum defined data set. *See* 45 C.F.R. § 162.925(a)(3) (''A health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan. . .'').

[21] ''Trading Partner Agreements'' CMS HIPAA Information Series, May 2003, Volume 1 – Paper 8, page 3.

[22] 63 Fed. Reg. at 25301.

[23] Id.

[24] By employing unnecessarily or inappropriately strict HIPAA data content edits, payers could also find themselves in violation of state ''prompt pay'' laws. These laws recognize that to deny or delay reimbursement solely because a claim contains immaterial errors or omissions is to elevate form over function at the expense of providers and their patients. Payers employing overly rigid HIPAA translators also run the risk of providers reverting to filing paper claims. For example, Virginia law requires payers to adjudicate ''clean claims''—claims that have ''no *material* defect or impropriety . . . which *substantially prevents* timely *payment* from being made''—in a timely manner. VA Code Ann. § 38.2-3407.15A (emphasis added).

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> [health care claim] (i.e., a subset of the HIPAA implementation guide data) they require or would prefer to have in order to efficiently adjudicate a claim.[25]

Support for a more flexible interpretation of the data content standards is also found in the discretion afforded by trading partners to process claims despite the absence of certain information. The Health Care Claim Status Request and Response (276/277) for example, permits payers to accept a claim in which the insured's name has been omitted, provided that the payer provides a report to the submitter that identifies the omission.[26] Indeed, there are literally hundreds of status codes that may be used by payers in reporting submission errors, the use of which does not prevent claim processing. Rigid legalistic definitions of the data content required in the submission of claims - or in any other transmission of data - should neither be required nor accepted under the TCSR.

By way of example, subscriber date of birth and Medicare assignment of benefit are ''required'' data elements under the health claim transaction. However, these data elements are frequently unavailable to the provider, or are otherwise unnecessary to the adjudication of the transaction. For HHS to interpret the TCSR as requiring trading partners to include these unavailable or unnecessary data elements in order to have a TCSR-compliant transaction is contrary to the provisions of the HIPAA statute, and to the administrative and operational realities of the health care system.

Furthermore, the Implementation Guides recognize the tremendous complexity regarding claims, and provide that the standard for inclusion of data elements within a submission is whether the information within the element is relevant to the claim. Addressing whether a data element that is marked ''situational''— and has no accompanying note to it regarding its status as a ''required'' element— should be sent, the IG advises that if the information is ''available and applicable to the claim,'' that it is recommended that the information be sent.[27] It should be beyond debate that any data elements – regardless of their purported status as ''required'' or ''situationally required'' – that reflect information that is either not available to one of the parties, or is not applicable to the claim – should not be interpreted by HHS as needing to be included within the data elements of a standard transaction.

V. Conclusion

Despite significant progress towards compliance with the TCRS, there is growing concern within the entire health care industry that the transition to standard transactions will cause serious disruptions to the health care payment system. Interruptions to cash flow will require diversions in management and administrative resources, and ultimately, will undermine the delivery and quality of patient care. Modest steps by HHS that do not require legislative or regulatory changes, can help minimize disruptions. Clear guidance on the data content issue will go a long way. Taking an unnecessarily restrictive view of the data content requirements, on the other hand, will likely engender increased administrative burdens, higher operating costs, and a decline in overall data quality, thereby jeopardizing the cost savings that— by federal statute—must be an essential component of any standards adopted by the Department.

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[25] ASC X12N-837 Health Care Claim: Institutional, Version 4010 (May 2000), at 12-13. We note that the commentary to the Regulation states that ''a required data element is always required in a transaction.'' 65 Fed. Reg. at 50322. The distinction between required and situational data elements is both governed and informed by the HIPAA statute. A ''required'' data element, in this context, should be understood as an element that trading partners may require in every claim, provided that it is reasonably necessary to process such claim. Contrast ''required'' data elements with ''situational'' data elements, which may be required only in specified circumstances. It is a basic tenet of administrative law that to be valid, regulations must be ''consistent with the statute under which they are promulgated.'' *See United States v. Larionoff,* 431 U.S. 864, 873 (1977). Consequently, the TCSR must be interpreted in light of the statutory requirement that ''[a]ny standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.'' 42 U.S.C. § 1320d-1(b). Flexibility in data content, within the parameters of the maximum data set, offers the best, and perhaps the only, way to reconcile the Regulation and the HIPAA statute.

[26] *See* ASC X12N-276/277 Health Care Claim Status Request and Response, Version 4010 (May 2000).

[27] ASC X12N-837 Health Care Claim: Institutional, Version 4010 (May 2000) at 41.