June 21, 2010

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RE: HR3590 Requirements for Financial and Administrative Transactions Subparts

Dear Distinguished Entities;

The National Council for Prescription Drug Programs (NCPDP) submits the following comments regarding HR3590 Requirements for Financial and Administrative Transactions Subparts.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,550 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

For over 30 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

Summary:
NCPDP with other organizations participated in discussions with Senate and House staff regarding several areas of concern related to HR3590.

"SEC. 1104. ADMINISTRATIVE SIMPLIFICATION.
(4) REQUIREMENTS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—
(A) IN GENERAL.—The standards and associated operating rules adopted by the Secretary shall—
(i) to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care;
(ii) be comprehensive, requiring minimal augmentation by paper or other communications;
(iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and
(iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields,

and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).*"*

Of concern is the bolded subsection (iv) above. The context of this letter is only the NCPDP standards named in HIPAA.

- We believe NCPDP has met the criteria in (iv) and recommend it be recognized as such.
- If NCPDP has not met these criteria, we seek clarification of what problem(s) this statement was trying to solve related to NCPDP standards named in HIPAA.
- Impact to the minimum data set requirements would need to be assessed.

Detail:

(iv) describe all data elements (including reason and remark codes) in unambiguous terms,

Points:

- NCPDP has met this criterion to the extent possible.
- The NCPDP ***Data Dictionary*** contains the data elements and associated attributes (field ID, name, size, format, definition, comments, etc.)
- The NCPDP ***External Code List*** contains the value set of each data element (value, definition, description) or the external reference if this isn't a code set NCPDP maintains (SNOMED, ICD-10, etc). Values brought forward by the industry must contain descriptions before publishing.
- NCPDP does not have reason and remark codes, but our Work Group 45 External Standards Assessment, Harmonization, and Implementation Guidance works closely with ASC X12 on areas where standards and external codes are used in X12 standards that the pharmacy industry uses (e.g. X12 835).

require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).

Points:

- NCPDP has met these criteria to the extent possible.
- The NCPDP ***Telecommunication Standard Implementation Guide version D.0*** represents the culmination of six years of industry working to consensus on clarification of transactions, data elements, data values, and situations of usage. We began work just after the HIPAA Privacy regulations were published that commented about required/situational/optional fields. This HHS/OCR comment was made **after** the original HIPAA Transaction versions were named and **after** the Transaction and Code Set regulations were published. Telecom version D.0 addresses this comment.
- The result of the industry work is the Telecom version D.0 contains 1200 pages of **rules, guidance, and examples**. Each transaction is explained in detail. Each segment within each transaction is stipulated. Data elements within each transaction have situations. There are many pages of explanatory information, guidance, questions, and many pages of examples to show different business cases.
- To support the Telecom guide, NCPDP publishes a freely available ***Version D Editorial*** document, which is updated quarterly, and contains frequently asked questions, examples, and further clarifications, as well as Medicare Part D needs, that the industry brings forward. Where possible, the information in the Version D Editorial is incorporated into future versions of the Telecom guide. We are currently balloting Telecom D.5 in anticipation of future HIPAA regulations. Standards continue to evolve as business requirements change, as clarifications are needed, and as questions are asked.
- NCPDP also publishes a ***Payer Template Implementation Guide***. It provides rules on the creation of the payer-specific information they need to share with their customers, within the bonds of the Telecom guide. Plans and payers use this template and guide to create their "payer sheets". Payer sheets are an important part of the pharmacy industry to relay important specific information. The pharmacy industry has used payer sheets for many years, and has had the NCPDP guide available since version 5.1.

- As a specific example of how the industry enhancements to the Telecom guide have benefited the industry, the MN Department of Health was regulated to build a "companion guide" for HIPAA transactions. After review of the Telecom D.0 guide, MN published regulations that cited the Telecom guide directly; there was no need to create a companion guide as the NCPDP documentation met their criteria and needs.

data elements be required or conditioned upon set values in other fields
Points:

- NCPDP has met these criteria to the extent possible. We believe that while this statement could be taken literally, that was not the intent. The industry has worked long and hard at coming to consensus on situational rules that reflect industry usage, but do not allow non-standard use of data elements. **It is not possible to make every conditional data element dependent upon set values in other fields. Data elements exist** that are constrained by business situations but cannot have a dependency on another field. These are examples of operational situations, which are stipulated in Telecom D.0, but cannot have a dependency on "another field". It is also important to note the real-time nature of the pharmacy transactions.
  - A pharmacy cannot send Medicare Part D information if the pharmacy does not have knowledge the patient has Part D coverage. The situation is stated in the guide, but is not dependent on "another field".
  - A pharmacy cannot send Workers' Compensation Segment if they are not filing a Workers' Compensation claim. The situation is stated in the guide, but is not dependent on "another field".
  - A processor cannot return Drug Utilization Review (DUR) information unless a conflict is found on the patient's history and medication files, not based on a given field value in the claim request.
  - A processor will return preferred product information that may assist the patient in choices when this information is based on the patient's benefit structure. It is based on a business case; not on dependencies of fields.
  - Situations defined for sending or responding with contract/pricing fields could violate contracts, if required to be shared by this regulation because they are not dependent on other fields. The industry worked long and hard on the payment and balancing rules of the claim.
  - Coordination of Benefits (COB) – A pharmacy cannot send other payer information if another payer doesn't exist. The guide has clear instructions on usage of the segment and fields and situations.

and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).

- The Telecom guide clearly states the situations must be followed. Additional conditions are not supported.
- The Telecom guide clearly has situations that state the usage of the field for regulatory requirements.

Other Important Points:

- Again, we support the intent of making standards and data fields as clear as possible. However we do not believe this statement was intended to be interpreted literally for every field.
- Requiring additional information affects the minimum data set. A primary goal of the original HIPAA mandate was to require only necessary data elements. This was partially due to privacy concerns and partially due to the recognition that forcing the exchange of data not meaningful to certain trading partners would not be classified as "administrative simplification" but would instead increase both cost and complexity for all trading partners.
- Sending elements when it is not certain that the information is always available or pertinent. For example, contract or pricing fields would likely become required but a default (zeroes) would have to

be established and then transmitted by the pharmacy when this type of claim information is not stored in their system. There is no transaction data element to trigger their contractual requirements. Sending defaults is dangerous and creates significant concerns as a default (zeroes) in a pricing field implies no benefit or no qualification. A default in a pricing field does not imply not pertinent.

- It is very important to recognize that the publications of the Standards Development Organizations (SDOs) represent the work of volunteers of the industry. Before we undertake any additional work it is important for the volunteers to understand what the problem(s) are and what is trying to be solved that is not already being met.

Thank you for the opportunity to provide input.

For direct inquiries or questions related to this letter, please contact

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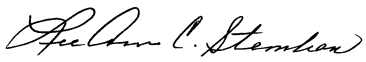
Sincerely,



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cc: NCPDP Board of Trustees