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The Value of the Current Change Request Process for Standards and Operating Rules

NCVHS Subcommittee on Standards

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Standards and Operating Rules Maintenance Process

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What is NCPDP?

- An ANSI-accredited standards development organization.
- Provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions.
- A member driven organization that has been named in various government legislation and rulings, such as HIPAA and the Medicare Part D Regulation.
- One of several Standards Development Organizations (SDOs) involved in Healthcare Information Technology and Standardization.
- Focus on pharmacy services, and has the highest member representation from the pharmacy services sector of healthcare.
- NCPDP standards are used in pharmacy processes, payer processes, electronic prescribing, rebates, and more.

- NCPDP dataQ™ - provides healthcare stakeholders with up-to-date, comprehensive, and in-depth pharmacy information.
- NCPDP Online - enumerator of the NCPDP Provider ID number.
- HCIdea - NCPDP's relational healthcare prescriber database of over 2.1 million prescribers created for the industry, by the industry.
- RxReco*nn*™ - NCPDP's legislative tracking product.

Current Process for Enhancements for All NCPDP Standards

Enhancements may be submitted by an NCPDP member or a non-member – any interested party

Enhancements are made via:

- An answer to a question that has been submitted to NCPDP staff or an NCPDP task group
  - After discussion, the question and solution may become a Data Element Request Form
- A submitted Data Element Request Form (DERF)
  - http://www.ncpdp.org/standard_changes.aspx
- A DSMO Change Request
  - Which is assigned to an NCPDP Work Group or Task Group.
  - After discussion, it may become a Data Element Request Form

The submitter is notified of the DERF process and is notified as the DERF moves through steps.

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Current Process for Enhancements for All NCPDP Implementation Specifications

- DERFs are adjudicated during the quarterly work group meetings.
  - *The submitter is invited to have representation at the meeting, or can discuss the request with the work group co-chairs or staff to represent them.*
- DERFs may be
  - Approved and proceed to ballot or publication
  - Pended due to follow up questions, research, etc
  - Denied with reason
- Balloting occurs with voting and public comment opportunities
- Ballots must
  - Meet approval requirements
  - Have comments adjudicated
  - Can be recirculated if substantial comments
- Upon approval, the implementation specifications are published

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Benefits of the current process

- The industry understands the process, or if new to NCPDP, we help to walk through and understand the steps.
- The DERF process was enhanced to support the DSMO CRS process.
- The regulatory process even fit in.
- Steps of the current process are used for operating rules enhancements as well.
- *A request for an enhancement needs a champion, otherwise why do it?*
- The process requires discussion and consensus at various levels to bring forward a solution that works for the industry.
  - Via task group conference calls
  - Via work group adjudication of DERF
  - Via ballot process
- There is an established process for working with ASC X12 on TR3s. There is collaboration with CORE, HL7, others.

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The Learning Curve

- Initially, standards regulation wasn't sought by the pharmacy industry, so education was provided many times on the DERF-DSMO-NCVHS-HHS process for HIPAA transactions.
- First round of HIPAA was painful
  - Privacy regs brought added requirements to the standards – after the standards were named
  - SDOs and the industry needed to learn how to be more nimble in the regulatory process
- NCPDP introduced steps within the standards development process to be more nimble with clarifications, modifications between regulatory cycles.
- Some change requests are brought to the DSMO, others directly to the SDO – *as it should be*.
- Effectiveness – With the introduction of the IFR process, the longest project step – the regulatory process – *has been improved*.
- There will always be a tension in implementation cycle timeframes - *implementation dates not soon enough for some, too soon for others, some want change, others not so much…..*

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Challenges – All Solvable

- Verify the Interim Final Rules for operating rules are clear for development and implementation processes.
  - Comments and recommendations submitted by industry
- Industry confusion "what is an operating rule?"
  - Develop educational criteria
    - If IFR cites entire document(s), some sections may be able to be clearly denoted as outside the scope of the implementation specifications and code sets. Then document which topics would be considered operating rules.
    - Many requests must start with the DSMO or SDO, as enhancements for the implementation specifications or a code set must be considered before becoming part of an operating rule.
  - Strongly recommend using the established process of the request coming through the DSMO, worked on by the organizations, then the DSMO recommends to NCVHS, then to HHS, then rule making.
- Collaboration and sharing of requests between the operating rule entit(ies) and the SDOs and Code Sets about industry need.
  - Change requests coming through the DSMO will help facilitate this.

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Challenges – All Solvable

- Working together to ensure that when a new version of the implementation specification is brought forward, that the operating rule document is brought forward (if affected).
  - Assisting HHS, industry in understanding when an operating rule may not need to be brought forward because the content did not change, or the enhancements were put into the implementation specification.
  - Strongly recommend using the established process of the request coming through the DSMO, worked on by the organizations, then the DSMO recommends to NCVHS, then to HHS, then rule making.
- Outreach to the industry
  - NCPDP task groups (conference call work) is open to any interested party
    - Telecom FAQ Task Group has over 200 participants
  - NCPDP focus groups to bring new parties together to problem solve, to broaden input
  - Notices in Federal Register of upcoming actions

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Challenges – All Solvable

- The industry has multiple routes to request enhancements. While some see this as confusing, a single threaded approach is not the solution and would not be efficient or effective.
  - Change requests coming through the DSMO will facilitate this.
- Champions can use routes they are comfortable with to seek action – through their professional associations, through website portals, through their vendor or trading partners.
  - Public access is available via NCPDP task groups, SDO portals, etc
  - *The champion has to be involved.*
  - *Get the need documented and into the existing process, wherever appropriate.*
- The enhancement comes through the SDO for the implementation specifications, and then to the DSMO for the start of the regulatory processes.
  - *So wherever it is initiated, the end result is moving the enhancement forward through the industry processes, with consensus and balance.*

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Challenges – All Solvable

- Frequency of changes – is the process too slow?
  - NCPDP reviews requests four times a year.
    - In 2010, NCPDP reviewed over 60 requests for enhancements.
    - Telecom is already at version D.9
    - SCRIPT went past version 10.11 and is on a new version identifier of CCYYMM
  - NCPDP processes ballots four times a year.
    - In 2010, NCPDP processed over 12 ballots.
  - *The changes are applied as brought forward, but it is important to note – <u>The industry may not wish to implement more than once every couple of years.</u>*
  - NCPDP submitted 9 DSMO Change Requests over the years – either on HIPAA Policy, or requesting a standard or new version to be named.
  - NCPDP, ASC X12, and HL7 brought forward the “Streamlining HIPAA” document. A result? The IFR process.
  - NCPDP is committed to working with the DSMO on finding efficiencies to the DSMO process.

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Thank You

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