NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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Lorraine Doo
Senior Policy Advisor
Centers for Medicare & Medicaid Services
National Standards Group
Office of Enterprise Information
7500 Security Boulevard
MS S2-25-15
Baltimore, MD 21244-1850

Re: National Committee on Vital and Health Statistics (NCVHS) Hearing on NCPDP Standards Updates

Dear Ms. Doo:

On behalf of our members, NACDS wants to thank the NCVHS and its Standards Subcommittee for the opportunity to present our views on industry implementation of the new HIPAA Standards: NCPDP Telecommunications Standard Version F2 and NCPDP Batch Standard Implementation Guide Version 15.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit www.NACDS.org

NCPDP Telecommunication Standard Importance and Impact

The NCPDP Telecommunication Standard is the major HIPAA standard used by our pharmacy members today. It includes transactions for Medicare Part D eligibility verification (the "E1"), claim and service billing, predetermination of pharmacy benefits, prior authorization, and information reporting. Pharmacies submitted over 3 billion claim transactions in real time last year using the NCPDP Telecommunication Standard vD.0. That does not include Medicare Part D beneficiary eligibility inquiries to the Medicare Part D Transaction Facilitator. The standard is a "real-time" transaction and allows pharmacies to verify eligibility, determine insurance coverage, learn if alternative medications are on the patient's drug formulary, and inform the patient of their required copay and submit the claim, all in under three seconds.

Since this is a real-time transaction at the point-of-care, patient care and the patient experience are quite dependent upon a successful transition. So, one can imagine that if a new version of the

standard is necessary, a successful implementation and transition to the new version of the standard is of major importance to patients as well as our members.

Benefits of the Proposed F2 Standard

After receiving this invitation to testify, NACDS worked with our members to obtain their viewpoints on the necessity of moving to a new version of the Telecommunication standard. Although a large, expensive, and time-consuming project, our members are overall supportive of moving to the F2 version of the Telecommunication standard, citing the following benefits:

- Increased patient safety;
- Improved pharmacy workflow automation and efficiency;
- Enhanced ability to comply with new federal and state regulations, including Medicare and controlled substance regulations; and
- Greater transparency between trading partners.

As a result of changes in the regulatory, technical, and operational environment since D.0 was implemented, our member pharmacies have brought forth to NCPDP modifications needed to D.0 to better address emerging pharmacy business needs in the next version of the standard. The new F2 version of the Telecommunication standard incorporates many of the incremental changes to the D.0 version suggested by our members. Because some of those changes have become quite necessary, NACDS encourages HHS to name the NCPDP Telecommunication Standard Version F2 and the NCPDP Batch Standard Implementation Guide Version 15 for pharmacy real time and batch claims billing.

Some of the changes to the F2 standard that benefit our members and patient care are listed below:

- Improvements to many of the Response segments in the new standard will replace or supplement text messaging with codified information. This change to codified information better supports pharmacy workflow automation. The workflow enhancements may also result in a reduction in patient waiting time and improvement in care. Additionally, we can expect more accurate communication to the pharmacy by the processor/PBM and by the pharmacy to the patient.

- Modifications to Coordination of Benefits (COB) fields and segments better support the maturing pharmacy COB environment and assist pharmacy providers and downstream payers in making claim billing decisions. These modifications better ensure accurate billing and reimbursement, improve record keeping, and enhance communication with patients.

- Enhancements to the Eligibility transaction (E1) better supports CMS' augmentation of eligibility data provided to pharmacies by the Medicare Part D Transaction Facilitator. This more robust eligibility information will better ensure accurate patient and benefit identification, assist in coordination of benefits, and enable pharmacists to better communicate

eligibility and benefit information to the patient.

- Changes to the Claim Billing and Response Claim segments provide additional information to enhance patient safety controls for controlled substance prescriptions. The new standard informs the processor/PBM of the exact prescription quantity and fill information, improves edits from the processor/PBM, and reduces confusion that can occur today and that sometimes requires patients to obtain a new prescription. The new standard also includes a discrete field to submit the prescriber's DEA number for controlled substance prescriptions.

- Additional information in the Response Claim segment sent to the pharmacy supports the identification of the reason for payer-directed formulary alternatives and of the required medication therapy. The specific fields also allow pharmacy systems to trigger the appropriate workflow actions. Electronic communication of these plan benefit parameters will reduce pharmacy calls to help desks, expedite patient access to care, and facilitate compliance with plan policies.

- New Pricing segment fields in the Claim Billing Request and Response transactions improve the identification and flexibility of changes related to tax and regulatory fees. There is more clarity around the type of tax or fee submitted and paid as well as tax exemption status. Pharmacies can more clearly communicate these taxes and fees to the patient.

- More comprehensive processor/PBM communication of their help desk contact information to the pharmacy will streamline communication protocols and claim resolution processes. This also enhances pharmacy workflow, communication with the patient, and the patient experience.

- As a result of regulatory requirements and the need for prescriptive authority validation at the time of dispensing, changes to the Prescriber segment were made. These changes allow pharmacies to better confirm prescribers have the proper prescriptive authority, support Medicare and Medicaid compliance, and reduce the impact of point of service conflicts on the patient.

- A new "Intermediary" segment was created to assist pharmacies in supporting manufacturers' FDA Risk Evaluation and Mitigation Strategy (REMS) processes. When implemented, pharmacies will access REMS information from participating REMS administrators within the pharmacy dispensing and claims processing workflow, augmenting REMS compliance and resulting in greater assurance that the patient benefits of a drug or biological product outweigh its risks.

Implementation and Transition to a new HIPAA Standard

As previously stated, over 3 billion prescription drug claims utilize the NCPDP Telecommunication standard transaction each year. That is over 8 million each day, impacting tens of thousands of patients each hour. Our members' implementation project plans for the transition to a new standard include contingency plans that put patient access to care as the highest priority.

The HIPAA statute provides for a two-year implementation window for health plans and providers after publication of a final rule. We believe that this is not adequate time to complete the business planning, systems development, testing, and the pharmacy chainwide rollout necessary for a successful implementation. Adequate time for (1) voluntary transition to the new standard between willing trading partners, (2) pharmacy rollout, and (3) the ability for trading partners to revert back to D.0 if something unforeseen occurs is of paramount importance to reduce potential impact on patient access to care. During the transition period, it is likely both versions of the standard will be used concurrently by processor/PBMs and pharmacies, depending upon whether both trading partners are ready to transition to F2.

It is also critical not to set important milestones (or the Compliance Date) during those times of year when industry resources are stretched due to the flu season and annual benefit change activity. We suggest avoiding November 15 – January 30 and considering the second quarter of the year. Finally, we encourage CMS to reach out to state Medicaid agencies and to urge states to begin their planning and preparation for budgeting now. We are confident that more states will be able to participate in the voluntary use time period and meet the Regulatory Compliance Date with earlier planning.

NACDS and many of our members have been actively engaged in the NCPDP implementation planning process to arrive at what our industry sector believes is a suitable timeframe and transition period. NCPDP has taken industry concerns into account in their proposed implementation plan and we are recommending that the Subcommittee and HHS follow NCPDP's proposed timeline.

In summary, NACDS supports the transaction from D.0 to F2 and the associated Batch Standard Implementation Guide Version 15, within the timeline proposed by NCPDP. We thank NCVHS for the opportunity to comment on this important issue. We look forward to working to ensure that these standards enhance pharmacy operations as well as increase patient safety and patient access to healthcare.

Sincerely,

Kevin N. Nicholson, R.Ph., J.D.
Vice President
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