



Date: June 3, 2019

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of the Administrator
Alexandra Mugge - Acting Chief Health Informatics Officer
MS: C5-02-00
7500 Security Blvd
Baltimore, MD 21244

Re: CMS-9115-P Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers

Dear Ms. Mugge:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP is providing the following comments regarding the CMS-9115-P Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers. NCPDP recommends CMS continue to collaborate with ANSI-accredited SDOs that create standards using a consensus process among industry experts to develop standardized, workable solutions.

Section I – E – 1 Patient Identifier and Interoperability

CMS:

“We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard. Recognizing Congress’ statement regarding patient matching and stakeholder

comments stating that a patient matching solution would accomplish the goals of a UPI, we seek comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We also seek comment on how we may leverage our program authority to provide support to those working to improve patient matching. In addition, we intend to use comments for the development of policy and future rulemaking.”

NCPDP Comments:

NCPDP agrees with previous commenters that the lack of a consistently used patient matching strategy has significant consequences for patient safety as well as financial, operational and regulatory inefficiencies. NCPDP encourages CMS to explore implementation of a solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries.

NCPDP has developed a solution, in partnership with Experian Health, to manage patient identities through a referential matching process. NCPDP’s Universal Patient Identifier® (UPI) leverages Experian’s expansive consumer demographic information and referential matching methodologies to identify record matches and duplicates in a patient roster file, and then assign a unique NCPDP UPI® to each patient in the file. The NCPDP UPI® can be used to exchange information amongst different healthcare entities. The joint offering addresses patient safety, financial and operational challenges across the U.S. healthcare ecosystem.

The following NCPDP Standards were identified as being applicable for communicating the NCPDP UPI® and were modified accordingly:

1. Post Adjudication Standard
2. Prescription Drug Monitoring Programs (PDMP) Reporting Standard
3. Prescription Transfer Standard
4. Prior Authorization Transfer Standard
5. SCRIPT Standard
6. Specialized Standard
7. Specialty Data Reporting Standard
8. Telecommunication Standard
9. Uniform Healthcare Payer Data Standard
10. Batch Standard Subrogation Standard

The Audit, Billing Unit, Formulary & Benefit, Product Identifiers, Retiree Drug Subsidy, UCF/Workers Comp Claim Form, Financial Information Reporting and Rebate Standards are the only standards that have been determined to not be applicable at this time. At such time these or any future standards are determined to be applicable, the NCPDP UPI® will be added to them.

Through its real-time and interoperable Telecommunication Standard and SCRIPT Standard, NCPDP has the unique ability to propagate the UPI throughout the pharmacy system and ultimately throughout the entire healthcare ecosystem. As multiple organizations acquire the NCPDP UPI® in their patient files, it can be transmitted in real-time transactions and then appended by other healthcare partners. The NCPDP UPI® can travel with a patient from provider to provider.

The NCPDP UPI® was developed by the industry, using the same consensus-building process that we use for federally mandated standards and industry guidance documents.

NCPDP's UPI® is a pass-through number that is not known to the patient or the provider, thus addressing privacy protections.

1. The patient does not know that the NCPDP UPI® number is attached to his or her record.
2. The NCPDP UPI® is not intended to be a patient-facing number in an effort to prevent misuse of the identifier or for data reselling purposes. The service provider controls the sharing of the patient information based on the consent that the patient signs to allow his or her information to be given to family members and the health plan.
3. NCPDP UPI® was established to facilitate patient matching and does not exchange patient clinical information.

Additionally, Experian has safeguards and protocols in place to handle billions of sensitive data records and does not collect or share any clinical claims or diagnostic information.

The NCPDP UPI® is available to any healthcare organization that exchanges patient data. It establishes the foundation to empower the exchange of patient information, through effective patient matching, across the healthcare ecosystem. Improved patient matching will:

1. Reduce medical/medication errors and improve patient safety;
2. Improve care coordination, population health management, prescription drug monitoring programs (PDMP); and
3. Reduce human and financial resources needed to reconcile duplicate records and billing/claims errors.

NCPDP's UPI® combines referential matching methodologies with a unique patient identifier, that is only available within a healthcare system as a pass-through number. This unique combination increases match rates and addresses privacy concerns often associated with patient identifiers.

NCPDP encourages CMS to work with an ANSI-accredited SDO, such as NCPDP, to establish standards that facilitate the sharing of patient matching information across disparate healthcare organizations to reduce medical errors, improve patient safety, and achieve interoperability.

Section II – A – 3 Specific Technical Approach and Standards

CMS:

“We welcome public comment on the proposed alignment of standards in this proposed rule to those proposed for adoption by HHS through ONC’s 21st Century Cures Act proposed rule, as well as on the best method to provide support in identifying and implementing the applicable content and vocabulary standards for a given data element.”

NCPDP Comments:

NCPDP continues to collaborate with other SDOs to ensure alignment between standards and support of emerging frameworks such as FHIR®. NCPDP recommends that ONC and CMS continue to work with NCPDP and other SDOs to produce and promote standards that will further enhance the exchange of electronic health information to improve interoperability and usability and to reduce administrative burdens.

We welcome the CMS/ONC joint effort to align standards wherever possible. A common process must be developed where CMS and ONC can collaborate with stakeholders and SDOs to identify and adopt existing standards and to develop standards where gaps need to be addressed.

Section II – A – 3 Specific Technical Approach and Standards

CMS:

“Finally, while we believe that the proposed alignment of standards requirements in this proposed rule to those proposed by ONC for HHS adoption is the best approach, we seek public comment on an alternative by which CMS would separately adopt the proposed ONC standards identified throughout this proposed rule, as well as future interoperability, content and vocabulary standards. Seek comment on whether this alternative would present an unacceptable risk of misalignment of standards or versions of standards across HHS’ programs, and an assessment of the benefits or burdens of separately adopting new standards and incorporating updated versions of standards in CFR text on a program by program basis in separate regulations. Furthermore, we seek comment on: how such an option might impact health IT development timelines; how potential misalignment of standards over time across HHS might impact system implementation; and other factors related to the technical aspect of implementing these requirements.”

NCPDP Comments:

It is critical that all vocabulary and transaction standards named under rule or certification be in alignment. The alternative proposed by CMS could present an unacceptable misalignment of standards or versions of standards across HHS’ programs, causing undue burden and confusion throughout the healthcare industry.

NCPDP recommends that CMS continue to work with ONC, NCPDP, and other SDOs on an appropriate process for naming standards, the version to be adopted, and the implementation timeframe to further enhance the exchange of electronic health information to improve interoperability and usability while reducing administrative burdens.

To minimize the potential for standards misalignment, NCPDP encourages each standard be defined in one regulation and other regulations point to the defining regulation. "Standards alignment" must include implementation time lines.

CMS will need to partner with ONC on the proposed voluntary early adoption of some standards. CMS needs to have a voice in the decision of which new/updated standards will be included in ONC's ISA – it is possible that CMS requirements or concerns might not otherwise be known by ONC.

Section II – D Updates to Standards

CMS:

“Therefore, we propose in section III.C.2.b. of this proposed rule that an entity may use an updated version of a required standard so long as use of the updated version does not disrupt an end user’s ability to access the data available through the API proposed in section III.”

NCPDP Comments:

CMS’s proposal appears focused on highly modular standards/specifications such as FHIR®. However, since NCPDP Standards are not modular, the standards could not be adopted in this fashion. NCPDP would like to work with CMS on an alternative so corrections and addendums could be available in a timelier manner.

Section III – C – 2 – b API Technical Standard and Content and Vocabulary Standards

CMS:

“the open APIs required for these entities must make available formulary information (for MA-PD plans) or information about covered outpatient drugs and preferred drug lists (for state Medicaid and CHIP agencies, Medicaid managed care plans and CHIP managed care entities).”

NCPDP Comments:

NCPDP is working collaboratively with HL7®, the DaVinci Project, CMS, Mitre and the CARIN Alliance to develop a FHIR® based API leveraging the QHP API available at <https://github.com/CMSgov/QHP-provider-formulary-APIs/blob/master/README.md>.

Section IX. Provider Digital Contact Information

CMS:

Entire Section

NCPDP Comments:

Historically, there have been issues with data integrity and a lack of completeness in the NPPES data files (e.g., taxonomy). While we applaud CMS for taking the initiative to expand the use of the NPPES data, it is uncertain whether a public file is the appropriate location for information that will be used as a basis for interoperability.

Section XIII – B Solicitation of Comments

CMS:

“We are also seeking comment on how we may leverage our program authority to provide support to those working to improve patient matching. We specifically seek input on the following questions and the potential authority for the requirement:

1. .
2. .
3. .
4. .
5. .
6. Should CMS support connecting EHRs to other complementary verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

7. .”

NCPDP Comments:

NCPDP recommends CMS support efforts by EHRs to have reliable identity matching. The NCPDP UPI® could be used for this purpose. NCPDP’s UPI® leverages Experian’s expansive consumer demographic information and referential matching methodologies to identify record matches and duplicates in a patient roster file, and then assign a unique NCPDP UPI® to each patient in the file. This unique combination increases match rates and addresses privacy concerns often associated with patient identifiers. The NCPDP UPI® is only available within a healthcare system as a pass-through number and can be used to exchange information amongst different healthcare entities.

The NCPDP UPI® is available to any healthcare organization that exchanges patient data. It establishes the foundation to empower the exchange of patient information, through effective patient matching, across the healthcare ecosystem. Several NCPDP Standards have been modified, as detailed in prior comments, to allow the communication of the NCPDP UPI®. Additional qualifiers can be added to the appropriate field within the NCPDP Standards to allow any patient identifier to be shared to improve patient matching.

NCPDP encourages CMS to work with an ANSI-accredited SDO, such as NCPDP, to establish standards that facilitate the sharing of patient matching information across disparate healthcare organizations to reduce medical errors, improve patient safety and achieve interoperability.

Further, any identifier selected by CMS should be openly available to any healthcare organization that exchanges patient data. Additionally, if CMS chooses to not name a specific vendor product for this purpose, NCPDP recommends CMS provide the industry with a registry of CMS endorsed identity matching services or products. The registry should only contain products that meet reliability standards set by CMS or industry norms.

Section XVI. Regulatory Impact Analysis - D. Alternatives Considered

CMS:

“We determined it was most appropriate to propose a technical and standards framework that strikes a balance between these two ends of the spectrum, and to establish that we expect the standards framework to expand and mature as interoperability increases.”

NCPDP Comments:

NCPDP recommends CMS continue to work with ONC, NCPDP and other SDOs to produce and promote standards that will further enhance the exchange of electronic health information to improve interoperability and usability and to reduce administrative burdens.

In conclusion, NCPDP and its members would like to thank CMS for the opportunity to provide written comments on CMS-9115-P Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers.

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

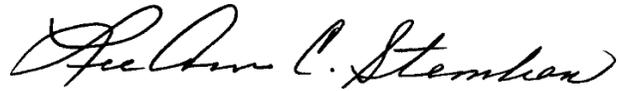
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Sincerely,



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