January 9, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RIN 0938-AT38

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the publication of the Notice of Proposed Rulemaking (NPRM) entitled "Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard" published on November 9, 2022. We appreciate the opportunity to offer our perspectives on this important proposed regulation.

WEDI, formed in 1991, is the leading authority on the use of health IT to improve health care information exchange to enhance the quality of care, improve efficiency, and reduce costs of our nation's healthcare system. WEDI's membership includes a broad coalition of organizations, including health plans, hospitals, other providers, vendors, government agencies, consumers, not-for-profit organizations, and standards development organizations. WEDI was designated in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislation as an advisor to the HHS Secretary.

CMS has proposed adopting updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of HIPAA. These updated versions would be modifications to the currently adopted standards for retail pharmacy transactions that include health care claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization, and coordination of benefits. The Agency is also proposing to expand the applicability of the Medicaid pharmacy subrogation transaction to all health plans and would rename and revise the definition of the transaction and adopt an updated standard. This would

be a modification for state Medicaid agencies and an initial standard for all other health plans.

We appreciate CMS moving forward with updating critical telecommunication and subrogation standards. Updating these important pharmacy transactions will result in decreased administrative burden and an improved care delivery process for patients.

We offer the following responses to specific provisions included in the proposed rule:

CMS Proposal

The NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15) would replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2). Version F6 includes a number of changes from Version D.0 that alter the use or structure of data fields, insert new data segments, and add new functionality. Adopting Version F6 to replace Version D.0 would constitute a HIPAA modification. We are proposing to adopt modifications to the current HIPAA retail pharmacy standards for the following transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. Covered entities conducting the following HIPAA transactions would be required to use Version F6:

- *Health care claims or equivalent encounter information (§ 162.1101).*
  ++ Retail pharmacy drug claims.
  ++ Retail pharmacy supplies and professional claims.
- *Eligibility for a health plan (§ 162.1201).*
  ++ Retail pharmacy drugs.
- *Referral certification and authorization (§ 162.1301).*
  ++ Retail pharmacy drugs.
- *Coordination of benefits (§ 162.1801).*

WEDI Response

WEDI supports the adoption of the NCPDP Telecommunication Standard Version F6 and Batch Standard Implementation Guide Version 15. We concur with CMS that these standards will provide significant benefits to the industry and most importantly, improve patient care. However, NCPDP has updated the standard and therefore recommend naming Telecommunication Standard Version F7 and Batch Standard Version 15 for health care claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization and coordination of benefits. We note that Telecommunication Version F7 is necessary to align with regulatory and health care needs by creating the distinction between administrative gender and clinical sex at birth.

CMS Proposal

(B) Proposed Modifications of the Pharmacy Subrogation Transaction Standard for State Medicaid Agencies and Initial Adoption of the Pharmacy Subrogation Standard for Non-Medicaid Health Plans.

1. *Proposed Modification to the Definition of Medicaid Subrogation Transaction (page 67640) Because we are proposing to broaden the scope of the subrogation transaction to apply to all health plans, not just state Medicaid agencies, we are proposing to revise the definition of the transaction. The Medicaid pharmacy subrogation transaction is defined at § 162.1901 as the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the state has paid on behalf of a Medicaid recipient. We are proposing to change the name of the transaction at § 162.1901 to the "Pharmacy subrogation transaction" and define the transaction as the transmission of a request for reimbursement of a pharmacy claim from a health plan that paid the claim, for which it did not have payment responsibility, to the health plan responsible for the claim*

WEDI Response

Medicaid is typically the payer of last resort and Medicaid subrogation is currently supported by defined payer order rules. We are concerned that there are no order rules for non-government payers in situations where a patient has coverage with multiple commercial plans. We recommend the Batch Standard Subrogation Implementation Guide v10 be required for Medicaid plans but be optional (not mandated) for non-Medicaid subrogation situations. We believe this will permit the pharmacy industry to ascertain if additional data elements (i.e., use cases, payer order rules and other guidance) are necessary. We assert that maintaining this flexibility would accelerate the adoption of electronic transactions to replace paper exchanges and the improvement of the standard for a larger variety of non-Medicaid subrogation.

Conclusion

WEDI applauds and supports the efforts of CMS to promulgate regulations to decrease administrative burden for health care stakeholders and improve care for patients. WEDI shares the Agency's commitment to facilitating health care data exchange and enhancing the ability of consumers to access accurate and actionable data. As the collective voice of the healthcare industry on health IT issues, we are pleased to continue our important partnership with CMS as you and your colleagues develop health IT regulations, industry guidance, and educational programming.

Please contact Charles Stellar, WEDI President and CEO, at 202.329.9700 or cstellar@wedi.org with any questions you may have on the issues we have raised in this comment letter.

Sincerely,
/s/
Ed Hafner
Chair, Board of Directors

cc: WEDI Board of Directors