March 1, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

Submitted electronically at http://www.regulations.gov

In reference to: *Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard – File code CMS-0053-P*

Dear Secretary Becerra,

As health IT consultants, Point-of-Care Partners (POCP) brings a unique perspective from providers, payers, and health IT vendors. POCP is a nationally recognized health IT (HIT) consulting firm with subject matter experts who have frequently testified before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical guidance to both the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC).

POCP continues to be at the forefront of standards development to advance the convergence of clinical and administrative data and the advances being sought within the industry and by regulators to progress data fluidity, data sharing and health information technology.

For over two decades, as members of the National Council for Prescription Drug Programs (NCPDP), POCP has helped shape the standards for prescription benefit Claims (Telecommunication), Electronic Prior Authorization (ePA) and ePrescribing (SCRIPT), Formulary and Benefit (F&B), and Real-Time Prescription Benefit Standard (RTPB). Our familiarity with the implementation requirements of these standards, and perspective as health IT management consultants, allows us to consider impacts of regulations for diverse stakeholders, including patients, providers, payers, life sciences companies and health IT vendors.

POCP SMEs currently co-lead the Da Vinci Project--a private multi-stakeholder initiative that is advancing HL7's FHIR standard to facilitate the exchange of clinical and administrative data in support of value-based care across payers, providers, technology vendors, and the entire healthcare industry. We also support the work of multi-stakeholder group, the FHIR at Scale Taskforce (*FAST*). *FAST* is aimed at helping identify and address infrastructure barriers to scalable FHIR solutions. In addition, the POCP team also is working to advance interoperability through extending the use of FHIR with project leadership, support, and guidance to advance standards within oncology and other domains through the HL7 FHIR Accelerator, CodeX. POCP is also the program management organization for the Gravity Project focused on identifying and harmonizing social risk factor data for interoperable electronic health information exchange.

POCP SMEs have worked diligently over the years on previous failed attempts to leverage existing X12 278 as a production solution to support prior authorization. It is in part, due to this effort that POCP is not in agreement with the provisions and recommendations found in this proposed rule. Further, we contend that the recommendations will limit progress towards data automation rather than advancing it and is out of sync with what is being progressed in

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the industry, by other standards development organizations, and contrary to the interoperability focus of other recent HHS proposed and finalized rulemaking.

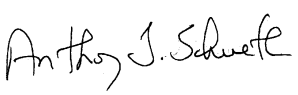
We recognize that Consolidated Clinical Document Architecture (C-CDA) is currently the most commonly used format for health information exchange. We appreciate that many health care stakeholders have invested in and are successfully using C-CDA technology without a regulatory requirement to use it. Payers and providers, along with the clearinghouses and data repositories they work with, can integrate data from C-CDA files into internal systems, including EHRs or claims processing systems. Yet, the cost-per-document to extract, transform, and load the data is expensive mostly because it's labor-intensive. Another limitation of C-CDA-based data is that once the extract transform load has been completed and the data is accessible, it remains trapped in the new location and is either invisible or unusable to any other health care stakeholders who might need to access the data to provide patient care or provider reimbursement. C-CDA technology will never achieve the efficiencies of fully automated, resource-based data that is machine readable, like API-based data exchange will support.

The proposed rule contains a recommendation to name and use standards for digital signatures. We question the need for an electronic signature standard when the industry has moved towards creating trust frameworks with partners to reduce administrative burden and multiple, redundant layers of confirmation as a part of healthcare digital transactions. As health IT consultants, POCP has worked with numerous organizations and served as contributors to HL7 FHIR and other health IT accelerators where industry stakeholders discuss the redundancies of electronic signatures. Most provider-payer relationships include the legal bindings of business agreements (Bas) and standard operating procedures (SOPs). All digital transactions between these organizations are verified by the contract users' IP-addresses as part of the BA or SOP. If data is shared between trusted and verified networks, why is there a need for further authentication via electronic signature? We object to the recommended adoption of HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1 Digital Signatures Guide because we do not believe this level of authentication is necessary or productive when data is being exchanged between two entities who have already signed BAs or SOPs. We do not believe a standard for electronic signatures is necessary.

In summary, we believe that value-based health care demands greater access to clinical and administrative data and real-time patient specific information. Access to real-time, discrete health information across multiple provider, payer and community resource networks is the most essential element in reducing administrative burden, improving care collaboration, and improving health equity. Modern standards, such as FHIR, active development and implementation of API based exchange will provide a clear path to the level of automation and burden reduction all parties so desperately need.

We are committed to advancing the exchange of patient health information and appreciate the opportunity to provide comments in response to this proposed rulemaking. Please reach out if we can answer any questions. We would be glad to provide further explanations or participate in discussions regarding this proposed rule.

Sincerely,



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