August 20, 2020

Demetrios Kouzoukas
Principal Deputy Administrator and Director
Centers for Medicare and Medicaid Services
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RE: HPMS 4189 Secure Electronic Prior Authorization for Medicare Part D Final Rule

Dear Principal Deputy Administrator Kouzoukas:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 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.

On June 22, 2020, via HPMS Secure Electronic Prior Authorization for Medicare Part D Final Rule memo, the Centers for Medicare and Medicaid Services (CMS) indicated a final rule regarding electronic prior authorization (ePA) would not be forthcoming as expected. Having invested thousands of member volunteer hours developing and driving adoption of ePA standard transactions, NCPDP is disappointed with this decision, but we understand the urgency and resource constraints that responding to the public health emergency (PHE) places on CMS and the industry.

On August 16, 2019, NCPDP provided comments to CMS supporting the forward movement by the Agency to finalize rulemaking adopting the use of the NCPDP SCRIPT Standard to facilitate the ePA process for medications. NCPDP recommends that CMS moves forward by establishing a final date for the adoption of the NCPDP SCRIPT Standard to facilitate ePA for medications to solidify and advance patients' expeditious access to their needed drug therapies and to further reduce the administrative load on all parties. Further delay would be a destabilizer towards burden reduction goals of the Administrator. Although there has been an encouraging uptake of pharmacy benefit prior authorization since the NCPDP SCRIPT standard for ePA was released in 2013, the industry will deprioritize this important work without a regulatory driver.

In our August 2019 comments, we outlined several key points:

*"As we shared in our previous communication, the NCPDP SCRIPT ePA transactions have been adopted by more than 60% of pharmacy benefit managers (https://epascorecard.covermymeds.com/). The use of these transactions significantly reduce the determination time of prior authorizations to hours instead of days. This leads to expedited access to therapy for the patient and results in improved outcomes.*

*Extensive due diligence has shown the X12N 278 transaction is not sufficient for ePrescribing workflows. NCPDP began work to create the NCPDP SCRIPT ePA transactions as a result of an ePrescribing pilot conducted in 2006 that evaluated the efficacy of the X12N 278 and X12N 275 transactions. The pilot found the X12N transactions were sub-optimal for the support of prior authorizations for medications and did not offer improvements in administrative efficiency."*

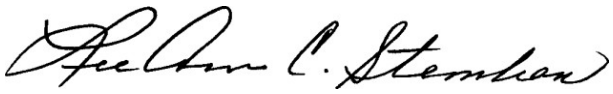
With the enactment of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, there are now **legal requirements to fight the opioid crisis** to ensure pain therapy patients can receive expeditious, automated approval of their medication.

- CMS' support of NCPDP SCRIPT ePA is an important step to validate and recognize progress towards automation and reduce provider burden. Without a named standard, the industry will continue to implement a variety of technologies and transaction protocols to ease provider and payer burdens.
- The **industry follows CMS' leadership**. The implementation community will fall in line and prioritize further automation in commercial lines of business. With the **absence of regulations, implementers will delay adoption** and slow down momentum and meaningful progress.
- The industry fully supports electronic prior authorization and **payers, providers and vendors are at the ready** to coalesce around a single standard.
    - Medicare adoption of NCPDP SCRIPT ePA will accelerate industry progress towards full automation between electronic medical records and payers.
    - **A Part D regulation is a stepping-stone towards broader adoption**. The industry needs to be able to assume a base level of standardized ePA support across systems to achieve full adoption. Uncertainty around regulations and standards creates a patchwork of support across the nation and forces providers and payers to support multiple workflows to process prior authorizations.
- CMS' support of technologies related to ePrescribing is critical to ensuring continued adoption of ePrescribing and Electronic Prescriptions for Controlled Substances (EPCS). Prescribers need to process prior authorizations safely and securely for opioids to ensure safe prescribing and dispensing. Forward progress on ePrescribing, especially amongst EPCS transactions, is inherently tied to ePA. Finalizing the rule to use NCPDP SCRIPT ePA aligns with CMS' overarching goals through programs like *Patients over Paperwork* and the newly created Office of Burden Reduction & Health Informatics, thereby enabling providers to focus on patient care.

While early adopters across payers, providers and vendors have embraced the existing NCPDP standard for ePA, it is imperative CMS acknowledge the progress and promise of pharmacy prior authorization automation to gain full utilization and adoption of the standard. Failure to support the complete suite of transactions required for full electronic prescribing requiring ePA as electronic transactions as required by current law and aligned with CMS' goals for burden reduction, patients over paperwork, prescription abandonment and administrative simplification is a step backwards. It is critical CMS keeps laser focus on the progress underway to gain the benefits of the collective investments of the industry. Given the current impact of COVID-19 PHE, NCPDP can appreciate the need for a delay in the required use or a

delayed enforcement of such requirement; however, NCPDP recommends that CMS move forward with the final rule naming of the NCPDP SCRIPT Standard ePA transactions.

Sincerely,



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Additional Information:
Comments to CMS-4189-P Medicare Program; Secure Electronic Prior Authorization for Medicare Part D
NCVHS testimony
Intersection of Clinical and Administrative Data Task Force