July 13, 2020

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2482-P
P.O. Box 8016
Baltimore, MD 21244-8016
Submitted to http://www.regulations.gov

RE: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-P; RIN 0938/Docket No. CMS-2020-0072)

To Whom It May Concern:

The National Council for Prescription Drug Programs (NCPDP) respectfully submits the following comments regarding CMS's proposed rule for Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-P) dated June 19, 2020.

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.

For over 30 years, NCPDP has been committed to furthering the electronic exchange of information among healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry, as named in the Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards used in electronic prescribing.

Our organization represents a number of different member perspectives with respect to the proposed rule under consideration. Although NCPDP's members are free to share their own opinions regarding the CMS rule, either directly or through their professional or trade associations, NCPDP's comments are general in nature and are limited to the organization's special role and expertise related to Section I: Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (§§ 456.700 Through 456.725), Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs That Provide Covered Outpatient Drugs (§ 438.3(s)). NCPDP offers the following for consideration.

> NCPDP is the SDO that creates and maintains the Telecommunication Version D.0 standard, the HIPAA-named standard for claims billing submission and response. The standard allows implementation of the edits which enforce rules such as initial days' supply limitations for opioid naïve beneficiaries, Morphine Milligram Equivalient (MME) limits and early refill limits for programs already in existence. NCPDP endorses CMS's efforts to combat the opioid crisis to ensure minimally adequate DUR programs are implemented

within the state Medicaids. NCPDP agrees that these programs should be appropriate, medically necessary and not likely to result in adverse medical results. However, NCPDP suggests that to tackle the opioid crisis nationally, it would be prudent tostipulate uniform limits or reporting requirements across Medicare Part D and all Medicaid programs instead of allowing Medicaid programs to create unique policies for their state or jurisdiction.

Any unique state Medicaid policies that vary from the Medicare Part D policy could require the addition of new or modified external code set values maintained by NCPDP. Specific opioid quantity limits may fall into this category as this is not a current requirement in Medicare Part D policy. Implementation of new values will take a minimum of 9-12 months.

When CMS releases a final rule, NCPDP encourages CMS to consider the following:

- Stipulate a defined minimum period of time (look-back) consistent with Medicare Part D policy that a Medicaid program would review before labeling a patient as opioid naïve.
- Define or identify guidelines for appropriate use of antipsychotics in children.
  Harmonize the diverse policies concerning Naloxone prescribing and dispensing when proposing rules related to Naloxone.

NCPDP strives to be a partner in combating the opioid crisis, while still being mindful of preserving access to care and patient safety. Accordingly, NCPDP thanks CMS for the opportunity to submit these comments on the CMS proposed rule.

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

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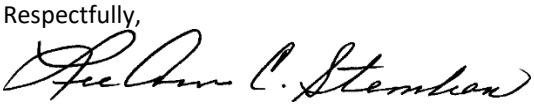
Respectfully,



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