TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

January 9, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Via: *Federal Register* at https://www.regulations.gov

RE: 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

Dear Secretary Becerra,

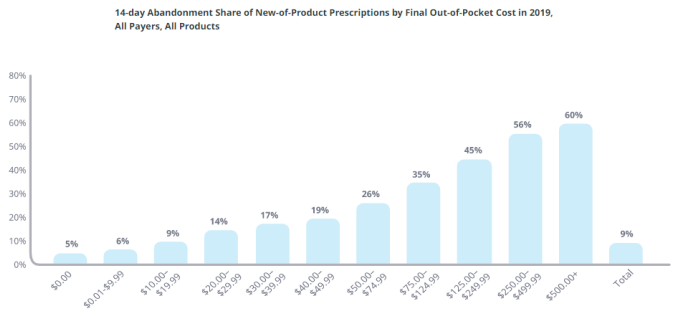
The Texas Medical Association (TMA), which represents more than 57,000 physician and medical student members, appreciates the opportunity to comment on the Department of Health and Human Services (HHS) proposed rule related to modification of the National Council for Prescription Drug Programs retail pharmacy standards posted to the *Federal Register* on Nov. 9, 2022.

Overarching Comments

TMA recognizes prescription drug costs can seriously impact a patient's financial and medical well-being, and a growing public health concern is the cost of prescriptions. Research has shown that medication abandonment rates correlate with prescription costs as indicated in Figure 1.

*Figure 1*

**A growing public health concern is patients abandoning their new prescriptions and not following a physician's recommendation for care. Abandonment occurs much more often when patient's have higher out-of-pocket cost.**




Source: IQVIA LAAD Sample Claims Data, Dec 20199
Notes: New to product prescriptions are those where patients have not had a prescription for the specific brand or generic drug within the prior year. Pharmacies in the sample provide information on prescriptions which were prepared for dispensing and whether they were dispensed, with abandonment defined as the prescription in question not being dispensed to the patient within 14 days of the initial fill.
Report: Medicine Spending and Affordability in the United States. IQVIA Institute for Human Data Science, August 2020

To help address these costs, it is important for pharmacies to be able to disclose to the patient the lowest cost option for the prescribed medication at that pharmacy. This should include available discounted prescription drug programs resulting in a reduced patient cost that is sometimes lower than when using the patient's health insurance prescription benefit.

Over the past several years, Congress and many state legislatures have taken action to ban certain contract clauses ("pharmacy gag clauses") that prevent a pharmacy from disclosing a lower out-of-pocket price option to the patient (e.g., the Patient Right to Know Drug Prices Act). These types of laws are important from both a patient cost-saving and medication adherence perspective.

Patients who do not adhere to their medication regimen add significant health care costs. According to a PubMed.gov[1] article, "the estimated annual cost of drug-related morbidity and mortality resulting from nonoptimized medication therapy was $528.4 billion, equivalent to 16% of total U.S. health care expenditures in 2016." The article proposes comprehensive medication management programs to mitigate avoidable costs and improve patient outcomes.

In alignment with these stated concerns, TMA policy supports patient access to affordable prescription medications. TMA will:

1. Support programs whose purpose is to contain the rising costs of prescription drugs provided that the following criteria are satisfied:
    (a) Physicians must have significant input into the development and maintenance of such programs;
    (b) Such programs must encourage optimum prescribing practices and quality of care;
    (c) All patients must have access to medically indicated prescription drugs necessary to treat their illnesses;
    (d) Physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and
    (e) Such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs.
2. Study the issue of drug pricing, including whether large price increases impact patient access to critical medications;
3. Support the application of greater oversight to the establishment of closed distribution systems for prescription drugs;
4. Support the mandatory provision of samples of approved out-of-patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays;
5. Work with interested parties to support legislation or regulatory changes that streamline and expedite the FDA approval process for generic drugs; and
6. Support measures that increase price transparency for generic and brand-name prescription drugs.

Another issue is that some pharmacies will not transfer a patient's prescription to another pharmacy when requested by the patient. Patients should be allowed to transfer a prescription to another pharmacy for any reason. Pharmacies that block easy transfers of medication could be impeding the patient's ability to access lower cost medications from another pharmacy. These types of transfers should not be blocked, regardless of health plan, and should not require extra effort from the prescribing physician or physician's staff. TMA believes that regulation allowing easy transfer of prescriptions will further spur price competition, help patients with medication access, and ultimately improve patient outcomes.

Furthermore, TMA encourages the Centers for Medicare & Medicaid Services to work with Congress to allow Medicare patients to use pharmaceutical discount cards and coupons in the same way commercially insured patients do.

Physicians nationwide are now required to use prescription drug monitoring programs for certain medications and electronic prescribing of controlled substances. These programs were put in place to help curb the opioid epidemic and have become an unfunded mandate. TMA pleads with HHS to seek ways to cover the additional costs of adoption and use of these technologies.

[1] Watanabe JH, McInnis T, Hirsch JD. Cost of Prescription Drug-Related Morbidity and Mortality. Ann Pharmacother. 2018 Sep;52(9):829-837. doi: 10.1177/1060028018765159. Epub 2018 Mar 26. PMID: 29577766.

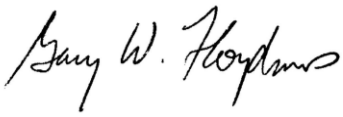
Specific Comment in Section III: Provisions of the Proposed Rule

In the section, *Codification of Clinical and Patient Data* (page 67,639), it is indicated that pharmacy and payer workflows are enhanced in Version F6 by replacing many clinical and non-clinical free-text fields in Pharmacy Claim and Payer Claim Response segments with discrete codified fields.

TMA is concerned that when removing free text and replacing it with discrete data fields, the information permitted may be too limited or is not well defined. Poorly designed discrete data fields potentially lead to unclear communication and confusion, which has patient-safety implications. Before deploying the discrete data fields, they should be broadly tested by both physicians and pharmacists to ensure clear communication. Additionally, the cost to update electronic health record and e-prescribing platforms to reflect these changes should not be passed on to physicians.

TMA appreciates the opportunity to provide feedback to HHS as regulations are finalized for retail pharmacy standards. Any questions may be directed to Shannon Vogel, associate vice president of health information technology, by emailing shannon.vogel@texmed.org or calling (512) 370-1411.

Sincerely,



Gary W. Floyd, MD
President
Texas Medical Association