

April 1, 2019

**VIA E-MAIL FILING**

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0055-P  
P.O. Box 8103  
Baltimore, MD 21244-1850

**RE: Administration Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) National Council for Prescription Drug Programs (“NCPDP”) D.0 Standard**

The American Association of Hip and Knee Surgeons (“AAHKS”) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (“CMS”) regarding the modification to the requirements for the Telecommunication Standard Implementation Guide, Version D Release 0 (“Version D.0”).

AAHKS is the foremost national specialty organization of more than 4,000 physicians with expertise in total joint arthroplasty (“TJA”) procedures. Many of our members conduct research in this area and are experts on the evidence based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by its three principles:

- Patient access, especially for high-risk patients, and physician incentives must remain a focus;
- Health care reform is most effective when physician-led; and
- The burden of excessive physician reporting on metrics detracts from care.

CMS solicits comments as to its proposal to require the Quantity Prescribed field in the August 2007 Version D.0 to be treated as a required field in efforts to enable covered entities to clearly distinguish partial fills and refill numbers in HIPAA regulated retail pharmacy transactions. In the proposed rule, CMS would treat the Quantity Prescribed Field in August 2007 Version D.0 standard as required for Schedule II drugs for the following three transactions: (1) Health Care claims or equivalent encounter information (2) referral certification and authorization; and (3) coordination of benefits. Additionally, the proposed rule would revise the definition of Schedule II drugs to mirror the Drug Enforcement Administration (“DEA”) definition.

## I. AAHKS Perspective on Opioid Prescribing Issues

It is well recognized that the United States is in the midst of an opioid crisis. The U.S. represents less than 5% of the world's population yet consumes approximately 80% of the world's prescription opioid production. In 2017, there were more deaths from opioid overdoses in the US than American deaths from the Vietnam, Afghanistan and Iraq wars combined.<sup>1</sup>

AAHKS is a committed partner and supporter of nation-wide efforts to reduce prescription drug misuse and overdose, including inappropriate use of opioids. As the root of this crisis is multifactorial, stakeholders across the health care and criminal justice systems all have important roles in this endeavor, including orthopaedic surgeons.

Our members are prescribers of opioids following TJA surgical procedures, but AAHKS has published a formal policy position that the use of opioids for the treatment of osteoarthritis of the hip and knee should be avoided and reserved for only for exceptional circumstances. In a subset of patients, prescribing opioids to help patients with pain from chronic conditions may contribute to an opioid dependency. The negative consequences of prolonged opioid use are well known. For patients who eventually choose to undergo hip or knee replacement surgery, these patients have difficulties with postoperative pain control, a higher risk of complications after surgery and potentially poorer long-term outcomes.

Further, AAHKS is developing opioid-sparing pain management standards for TJA. Our overall goal is to develop or identify three process, three structural, and three outcomes measures for the physician to use at their discretion to satisfy various reporting requirements. We support the proposed rule as a helpful step in nation-wide efforts to better address opioid misuse.

## II. Substantive Comments

AAHKS supports CMS efforts to provide health care stakeholders the ability to clarify the dispensed amounts of Schedule II drugs through the requirement of the Quantity Prescribed field for the following reasons:

**The proposed rule enables health plans pharmacies to accurately reflect prescription fills and therefore create a complete picture of patient pain management.** As referenced in the proposed rule, pharmacies and plans were unable to distinguish partial fills from refills. As a result, entities interpreted and recorded fill dates through several different perspectives. This discrepancy made reported data on opioid prescription fills ineffectual in assisting plans and the federal government in managing opioid risk and preventing inappropriately billed payments under Medicare Part D. The inability to accurately reflect partial refills for documentation strips away the power of payers and other stakeholders to accurately track the clinical decisions on opioid prescription dispensing amounts made by pharmacists, patients, and physicians. The

---

<sup>1</sup> Julie Vitkovskaya, *What is Fentanyl?*, Washington Post, March 13, 2019.

implementation of this rule will ensure that actual opioid prescription fill amounts can be accurately tracked in order to distinguish between authorized partial fills and inappropriate refills.

**Compliance with the proposed rule does not increase administrative burdens for stakeholders.** AAHKS believes that federal reforms exist to reduce opioid abuse while allowing for proper pain management and NOT increasing provider administrative burden. This proposed rule is an example of such reform. The proposed rule does not require covered entities to modify the presently adopted Version of D.O. or force the adoption of the 2012 publication of version D.O. Furthermore, the CMS proposal not recommend adoption of Version F2 because adopting it would delay the ability for covered entities to accurately capture partial fills of Schedule II drugs. This type of reform better enables health system compliance with opioid prescribing standards and will produce effective monitoring and management data.

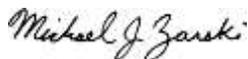
\*\*\*

AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at [mzarski@aahks.org](mailto:mzarski@aahks.org) or Joshua Kerr at [jkerr@aahks.org](mailto:jkerr@aahks.org).

Sincerely,



Michael P. Bolognesi, MD  
President



Michael J. Zarski, JD  
Executive Director