AMA
AMERICAN MEDICAL ASSOCIATION

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EXECUTIVE VICE PRESIDENT, CEO

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John Prince
Chief Executive Officer
OptumRx
2300 Main Street
Irvine, CA 92614

Dear Mr. Prince:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing with strong concern about OptumRx's pending action to only accept electronic prescriptions for controlled substances (EPCS) for home delivery as of January 1, 2020. As we recently discussed on a call between OptumRx staff, AMA staff, and colleagues from several medical societies, the AMA is greatly concerned that OptumRx's new policy will lead to considerable disruption in patient care given the fact that only about 44 percent of physicians currently have the technology, hardware and certifications required for EPCS.

We point out that if OptumRx does not delay implementation, patients in every state will likely suffer negative consequences from not having their necessary medications dispensed. This includes patients receiving care for opioid use disorder, anxiety, depression, attention deficit hyperactivity disorder, auto-immune diseases, HIV/AIDS and painful conditions like sickle cell disease. Losing access to medications to help treat chronic disease could have devastating, potentially fatal consequences. In addition, data shows wide disparities in pain treatment for minorities, and OptumRx's policy could exacerbate those disparities. We already have heard of significant concerns from physicians in several states that patients stable on medications may not be able to obtain them in a timely manner—or with cost increases—due to the pending OptumRx EPCS requirement.

There are additional reasons why the AMA believes OptumRx would be well-advised to delay implementation of this requirement.

First, while the AMA supports EPCS, there remain significant regulatory barriers that have prevented widespread EPCS uptake. The AMA has been urging the U.S. Drug Enforcement Administration (DEA) to update its requirements for the biometric component of multifactor authentication with respect to EPCS for a number of years. The SUPPORT Act requires the agency to modify these requirements, and the DEA is currently working to make these modifications. Requiring adoption of EPCS prior to these regulatory changes is likely to have many unintended consequences.

Second, as you are likely aware, Section 2003 of the federal SUPPORT Act requires, with certain exceptions, that covered drugs in Schedules II, III, IV and V prescribed to patients with Medicare Part D prescription drug coverage must be transmitted electronically in accordance with the DEA regulations for EPCS effective January 1, 2021. Not only has DEA not updated its regulations, but OptumRx's policy is not aligned with the timeframe of the federal law, which will likely lead to further market confusion and disruption.

Third, the misalignment of OptumRx's policy with the timeframe of federal law is multiplied by the fact that many states also have tied EPCS requirements to the January 1, 2021, federal Medicare Part D requirement. In addition to inserting itself into the regulatory framework of state licensees, Optum's January 1, 2020 date directly conflicts with state licensing and regulatory authority.

For these reasons, the AMA strongly urges OptumRx to delay its decision to require EPCS until, at the very earliest, after DEA updates its regulations. We further believe that OptumRx should not require EPCS in a state unless the state legislature and/or regulatory boards have approved such policy. In states where EPCS has been implemented, it has only been after careful consideration of the impact on patients in rural and underserved areas.

In addition, federal requirements in the SUPPORT Act allow for multiple exceptions for EPCS. State policies, moreover, have crafted additional exceptions and ways in which physicians and other health care professionals can apply for a waiver to the EPCS requirements. Those requirements would be reviewed by state officials to determine, among other things, whether the waiver is needed to ensure access to care for patients.

This is the appropriate action for a state, and we note that OptumRx's January 1, 2020 EPCS requirement has no apparent exception or waiver process that accounts for federal or state laws. We strongly oppose OptumRx instituting a corporate policy that overrides the careful deliberations that have informed federal law and take place between state legislators, health policy experts, patients and the health care community.

For these reasons, we strongly urge OptumRx to delay implementation of its January 1, 2020 EPCS requirement.

If you would like to discuss these matters in more detail, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,

James L. Madara, MD