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Ruth Fox, MD 1895-1989 October 18, 2019

Thomas Van Gilder, MD Chief Medical and Analytics Officer Walmart, Inc. 702 SW 8th Street Bentonville, AR 72716

Dear Dr. Van Gilder:

On behalf of the American Society of Addiction Medicine (ASAM), a medical specialty society representing over 6,000 healthcare professionals who specialize in the prevention and treatment of addiction, I would like to call your attention to the continued receipt of notices by ASAM members from Walmart Health and Wellness Practice Compliance, informing them that Walmart pharmacies will no longer fill their controlled medication prescriptions (see enclosed). While these notices mention pharmacists' "corresponding responsibility" set forth in 21 CFR 1306.04, unfortunately, they do not provide any specifics about the prescribing practices that warrant a refusal to fill prescriptions written by the notice recipients. This lack of key information, coupled with the frequency with which these notices are being received by addiction medicine practitioners, raises the possibility that legitimate prescriptions of buprenorphine, a drug commonly used to treat opioid use disorder (OUD), are not being filled by Walmart. Tragically, a sudden refusal to fill prescriptions of medications for addiction treatment can lead to adverse health outcomes for patients, including relapse and even death.

Buprenorphine is a partial opioid agonist that is commonly prescribed for the treatment of OUD. Relative to treatment without medication, office-based opioid treatment with buprenorphine improves six-month treatment engagement, significantly reduces cravings, illicit opioid use and mortality, and improves psychosocial outcomes. Importantly, agonist therapy has been shown to decrease mortality by approximately 50% among persons with opioid use disorder. The treatment of addiction differs from treating chronic pain, and the risks, benefits, and safe medication dosages of longitudinal treatment with opioids differ as well. Entities such as the Centers for Medicare & Medicaid Services (CMS) recognize a need to



treat medications for the treatment of OUD differently than medications indicated for pain and carve out buprenorphine for the treatment of OUD when evaluating patients' morphine milligram equivalents (MME) of opioids in policies aimed to curb opioid overutilization.

As was discussed in the November 8, 2017 meeting between ASAM and Walmart Health and Wellness Practice Compliance staff, ASAM has been concerned that Walmart's compliance practices may be inappropriately treating buprenorphine used for OUD no differently than opioid medications used for the treatment of pain. The prescribing and dispensing of medications used in the treatment of OUD is frequently conflated with the prescribing and dispensing of opioids for the treatment of pain, resulting in incorrect inferences about the appropriateness of quantities or treatments. The repeated refusal of Walmart to fill controlled substance prescriptions from addiction medicine practitioners causes ASAM to reiterate its concerns here.

To be clear, ASAM appreciates the legal obligations assigned to pharmacists under 21 C.F.R. 1306.04; however, without additional information as to how Walmart interprets those obligations as they relate to buprenorphine, practitioners are unable to predict when and how their patients will be able to obtain their needed medications. For that reason, ASAM respectfully requests that Walmart provide additional information as to the factors that can lead to the rejection of a practitioner's prescriptions for buprenorphine. In addition, ASAM welcomes more information regarding Walmart's decision-making process, so that it can better understand the specific interpretation or policy that is potentially creating a disconnect between appropriate clinical practice of addiction medicine and Walmart's Health and Wellness Compliance Practice.

Finally, in case helpful, ASAM will host a free webinar on October 30th at 3pm ET in collaboration with the American Pharmacists Association called "Buprenorphine 101: Physicians and Community Pharmacists Collaborating to Improve Access to Medication Assisted Treatment." This webinar is designed to educate pharmacists on the treatment of addiction, including highlighting examples of opioid analgesic prescribing "red flags" commonly used by pharmacists which are not necessarily appropriate in the context of buprenorphine prescribing for the treatment of OUD. ASAM encourages representatives from Walmart to attend this free webinar to learn more about the treatment of addiction. You can find more information about the webinar here.^{III} I thank you in advance for your attention to this matter, and ASAM looks forward to your response. Please do not hesitate to contact Becca Branum, ASAM's Senior Manager of State Advocacy and Government Relations, at bbranum@asam.org or at 301-547-4138.

Sincerely,

Paul H. Earley, MD, DFASAM

faul H Earley M.D.

President, American Society of Addiction Medicine



Enclosures:

Letter from Walmart Health & Wellness Practice Compliance dated May 17, 2017 Letter from Walmart Health & Wellness Practice Compliance dated August 9, 2019 November 8, 2017 ASAM/Walmart Meeting Agenda

¹ American Society of Addiction Medicine, Treatment Research Institute. (2013). FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness and Cost-Effectiveness. Chevy Chase, MD: American Society of Addiction Medicine. Available at https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final; Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2014, Issue 2. Art. No.: CD002207.

[&]quot;Schuckit MA. Treatment of Opioid-Use Disorders. N Engl J Med 2016; 375:357-368.

iii Registration available at: http://elearning.pharmacist.com/products/5718/buprenorphine-101-physicians-and-community-pharmacists-collaborating-to-improve-access-to-medication-assisted-treatment.



Health & Wellness Practice Compliance

702 SW 8th Street Bentonville, AR 72716-0230

May 17, 2017

Prescriber Name:
Address

Re: Controlled Substance Prescriptions

Dear John,

We are writing to inform you that Walmart and Sam's Club pharmacies will no longer be able to fill prescriptions that you write for controlled substances (Schedules II-V).

In our efforts to meet our compliance obligations, our pharmacist's corresponding responsibility under 21 CFR §1306.04, and to help combat prescription drug abuse and diversion, we routinely review the prescribing patterns and practices of the prescribers whose prescriptions are presented to us for filling. In reviewing your controlled substance prescribing patterns and other factors, we have determined that we will not be able to continue filling your controlled substance prescriptions. We will continue to review information related to controlled substance prescribing, and will inform you if our policies change. We regret any inconvenience this may cause to you or your patients.

Please direct any questions regarding this matter to RXCSComply@wal-mart.com or (479) 204-

Sincerely,

Health & Wellness Practice Compliance



Health & Wellness Practice Compliance

702 SW 8th Street Bentonville, AR 72716-0230

August 9, 2019



Re: Controlled Substance Prescriptions

Dear DR.

We are writing to inform you that Walmart and Sam's Club pharmacies will no longer be able to fill prescriptions that you write for controlled substances (Schedules II- V).

In our efforts to meet our compliance obligations, our pharmacist's corresponding responsibility under 21 CFR §1306.04, and to help combat prescription drug abuse and diversion, we routinely review the prescribing patterns and practices of the prescribers whose prescriptions are presented to us for filling. In reviewing your controlled substance prescribing patterns and other factors, we have determined that we will not be able to continue filling your controlled substance prescriptions. We will continue to review information related to controlled substance prescribing, and will inform you if our policies change. We regret any inconvenience this may cause to you or your patients.

Please direct any additional information you would like us to consider to:

RxCsComply@wal-mart.com

Sincerely,

Health & Wellness Practice Compliance



Agenda

ASAM Meeting with Walmart Health and Wellness Practice Compliance November 8, 2017

Time: 9:30 AM - 2:00 PM CST

WebEX Information:

Link: http://walmart.webex.com Meeting Number: **749 433 645** Meeting Password: **walmart**

Audio Connection: +1-855-797-9485

Access code: 749 433 645

Time	Item #	Item Description and Outcome
9:30 am - 9:40 am CT	1.	Welcome, Meeting Goals, and Introductions Dr. Clark and Wal-Mart officials will summarize their goals for the meeting. Attendees will have an opportunity to introduce themselves, their background, and their role in each of their organizations.
9:40 am - 10:00 am CT	2.	Understanding Walmart's Philosophy Miranda Johnson and George Chapman will provide a high level overview of Walmart's efforts to limit access to controlled substances used for illicit purposes, through review of prescribers patterns and practices, in keeping with the guidance outlined on CFR 1306.04.
10:00 am - 11:30 am CT	3.	Addiction Medicine Best Practices & the Addiction Medicine Workforce Dr. Jarvis will present the recommendations of the ASAM National Practice Guideline for the Use of Medications for the Treatment of Addiction Involving Opioid Use. Dr. Clark will provide an overview of the current addiction medicine workforce and discuss some of the unique challenges these clinicians face in meeting patient demand for treatment.
11:30 am- 12:30 pm CT	4.	Q&A Session

12:30 pm-	5.	Working Lunch
2:00 pm CT		Parties will discuss opportunities for ASAM and
		Wal-Mart to work together to promote
		evidence-based addiction treatment, ensure
		patient access to needed medications, and
		reduce prescription drug misuse and diversion.

ASAM In-Person Attendees:

Dr. Margaret Jarvis - Vice President

Dr. Shawn Ryan - Chair of Payer Relations Committee & President of Ohio Society of Addiction Medicine

Penny Mills - CEO & Executive Vice President

Corey Barton - Manager, Private Sector Relations

ASAM WebEx Attendees:

Dr. Kelly Clark - President

Kelly Corredor - Director of Advocacy and Government Relations

Wal-Mart Attendees:

George Chapman – Sr. Director Health & Wellness Practice Compliance Susanne Hiland - Sr. Director, Quality Improvement & Clinical Services Katrina Jamison – Sr. Director Operations Support & Communications Matt Holt – Sr. Director Operations Support – Sam's Club Miranda Johnson – Director Controlled Substance Practice Compliance Tim Koch – Sr. Director Health & Wellness Practice Compliance Rick Irby – Sr. Director Health & Wellness Practice Compliance Debbie Mack – Sr. Director Health & Wellness Practice Compliance Karen Davila – Sr. Associate Counsel – Legal Hudson Vanderhoff – Sr. Associate Counsel – Legal Jamie Newell – Sr. Manager Controlled Substance Practice Compliance Roxanne Reed – Sr. Manager Controlled Substance Practice Compliance