James L. Holly, M.D.

CVS Health Announces that through Their Pharmacy Benefit Management, Dispensing of Opioids Would be Limited to a 7-Day Supply An Annotated Summary of the Discussion to Date

On September 21, 2017, CVS Health announced that beginning in January and February of 2018, CVS Health's Care Mark, one of the nation's four largest Pharmacy Benefit Management (Plans (PBM) would begin dispensing only a 7-day supply of opioids without consultation with the prescribing physician. This will impact patients who receive their medications by mail and those who obtain medications by going to a pharmacy other than CVS Health. Not only will cost increase but this move measure is the opposite of what is known to improve patient adherence with their medicine, i.e., dispensing of 90-days of medications.

No doubt opioids and other potentially habituating medications are in a different class, but, as will be argued here, if opioids are being properly prescribed and properly used, they should be as easy to obtain as any other medication. The way to eliminate inappropriate use of opioids is not to obstruct patient access to these medications once they are prescribed; it is to stop the inappropriate and excessive prescribing of opioids.

This is a review of a ten-part discussion of these issues which results in my conclusion that CVS Health's Caremark plan is inappropriate, possibly illegal and an ineffective way of dealing with the opioid crisis in this country.

https://cvshealth.com/newsroom/press-releases/cvs-health-fighting-national-opioid-abuse-epidemic-with-enterprise-initiatives

Pm September 23, 2017, Southeast Texas Medical Associates, LLP (SETMA, LLP) sent a letter to Mr. Larry Merlo, CEO, CVS Health Caremark, briefly detailing SETMA's long standing efforts to eliminate inappropriate prescribing of opioids and making the following statement repeatedly: "Finally, if any medication, including opioids, is prescribed legally and appropriately, one should be as easy to obtain as another. The way to deal with opioid abuse is not by making legitimately prescribed opioids more difficult to obtain, but by auditing the prescribing of potentially habituating medications and by eliminating inappropriate prescribing."

CVS Plans to Change Prescriptions without Physician Approval - An Open Letter to CVS' CEO

On September 28, 2017, the letter to CVS's CEO was published as an open-letter in SETMA's weekly health column in the Beaumont Examiner. In addition to having distributed the letter to

over 500 healthcare leaders and consumers, this continued SETMA's effort to expand this discussion.

Letter to 105 Pharmacies in our 5-county Area about CVS and Opioids

On September 27, 2017, SETMA, LLP mailed a copy of the letter to CVS's CEO along with a cover letter to 105 pharmacies in our five county area. This letter stated: "I and SETMA has the highest regard for our pharmacist colleagues and we value their input to patient care. This is not a discussion about "turf," but about how to effectively unite our efforts to solve this problem."

CVS Health Response to Troy Brennan Letter and Health Affairs Blog

On September 28, 2017, SETMA's CEO received a response to the letter to CVS Caremark CEO from CVS Health's Executive Vice President and Chief Medical Officer, Troyen A. Brennan, M.D., M.P.H. In a 19-page response linked above, SETMA's CEO responded to Dr. Brennan. In a nine-part annotated document, SETMA reviewed our "preliminary conclusions" to this discussion, CVS Health's pledge not to get involved in primary care which promise they did not keep, a review of PBMs and CVS Health's past transgressions, a detailed review of Dr. Brennan's response to Dr. Holly, an analysis of Dr. Brennan's blog in Health Affairs, the CDC Primary Care Guidelines for Opioid Prescribing and a review of the Checklist for that Guideline.

SETMA's conclusions about CVS Health's Caremark's plans which were labeled as "preliminary" are now affirmed as final; they are:

"My overall conclusion is that CVS' effort to contribute to the abusive use of opioids is laudatory.

"However, while it may be considered that CVS' initiatives are healthy disruptive innovations in healthcare, there are serious questions about their violation of regulatory oversight involving their Pharmacy Benefits Management (PBM) Company and their pharmacists in overstepping their professional boundaries in patient care? Historically, the ideal of pharmacists/healthcare provider collaboration was a team dialogue. CVS appears to want to eliminate the team and have the pharmacy benefits manager, pharmacy, pharmacists and CVS retail stores, with captive employed Nurse Practitioners, take over healthcare. The deficiency of the care which is being provided by CVS retail stores is obvious to everyone except CVS.

"CVS is using their commercial enterprises to compete in a potentially monopolistic way with the primary care healthcare providers upon whom their commercial enterprises are dependent. It is possible that an organized effort on the part of physicians can direct their pharmaceutical business to other pharmacies which are not involved in competition with primary care providers.

"This reaction can extend to primary care physicians who are involved in managed care organizations who use CVS Caremark to demand that another PBM company be used. The very nature of illegal monopolies is that the size, influence and power of the perpetrator of the monopoly is insensitive to market demands. CVS' size and profitability has them in that position presently but their leverage. At the very least every healthcare provider who is participating in a

management care organization which contracts with a Pharmacy Benefits Manager should demand to know what utilization management tools are in place with the PBM which allows the physicians prescriptions and/or orders to be ignored without notification of or consultation with the healthcare provider.

"The image of a retail pharmacy chain, through their extensive commercial enterprise and their powerful PBM, "taking over" healthcare is alarming to me. As a healthcare provider who is involved in primary care, in patient-centered medical home, and in managed care which contracts with CVS' Caremark, I argued for years that the Affordable Care Act did not intrude between the provider and the patient. What I did not recognize was that an intrusion had taken place and is expanding and it is through the collaboration between HMOs and PBM and the retail, commercial stores which are owned by a PBM.

"At the least the following should happen:

- 1. Every healthcare provider and particularly every primary healthcare provider should demand to know the policy of PBMs for changing a physician's orders or prescription.
- 2. CVS Caremark must disclose its relationship with CVS' extensive primary care network, particularly as to whether CVS NPs will be employed in the counseling of patients who come to the pharmacy but which are referred to the NP for education, counseling or changing of the primary physicians orders.
- 3. All health plans should "opt out" of CVS Caremark's utilization management program which allows them to change physician orders or prescriptions without consultation with the physician.
- 4. The recommendations made in the 8th installment of SETMA's 2017 series on opioid abuse should be implemented. These can be read at: The Opioid Epidemic: Part VIII What is the Solution."

<u>Transmittal Letter to Final Copy of Analysis of CVS Health's Opioid Abuse Plan and Why it Should be Rejected</u>

This document is a summary to this point in the discussion about CVS Health's Caremark plan and is titled, "Why All Health Care Providers Should "Opt Out" of CVS Health's (Caremark) Opioid Abuse Prevention Plan." Presented in a slightly different format, this link essentially contains the same material as the previous one.

Summary of Analysis and Recommendations About CVS Health's Use of Their Pharmacy Benefits Management to Limit Opioid Dispensing

This link is entitled, "Summary of Analysis and Recommendations About CVS Health's Use of Their Pharmacy Benefits Management to Limit Opioid Dispensing." This is an intermediary effort to make access to this discussion more accessible. It is superseded now by this up to date summary.

Value, Virtue, Trust and Hope - The Foundation of Health Improvement

This is a 2015 article which addresses the empowerment of people to make and to sustain changes in their life. It is critical in the treatment of opioid addiction and abuse to understand the progression from a sense of personal value, to personal virtue (power to make and sustain a change), to trust and finally to the logical result of value-virtue-trust which is "hope."

CVS Health and Opioids - Dr. Lembke's Question About Pharmacists and Opioids and Dr. Holly's Response

During the Primary Care Week at UT Health Long School of Medicine from October 4-6th, there were presentations by the UT Health Center for Medical Humanities and Ethics. There were several presentations by Anna Lembke, MD, Medical Director, Addiction Medicine, Chief, Addiction Medicine Dual Diagnosis Clinic, Program Director, Addiction Medicine Fellowship. Associate Professor, Department of Psychiatry and Behavioral Sciences. Courtesy faculty appointment, Department of Anesthesiology and Pain Medicine, Stanford University School of Medicine.

This and the following exchanges took place by electronic mail, which places Dr. Lembke's comments at the end of the link and my response as the beginning.

Dr. Lembke asks what I think is the proper role for pharmacists in healthcare. I answer that question. In part my answer states: "It does not include a provision for pharmacists, pharmacy benefit managers (PBM), and/or primary care providers, employed by retail pharmacies, to counsel patients and or to limit access to medications when they do not have medical records of the patient, and do not have a HIPAA Compliant right to review the records which are available. For pharmacists who are filling a medication to contact the provider and to question the prescription, in my judgment is excellent. This is what happens with the staff pharmacist in a nursing home recommends a change in a medicine. A verbal or written communication takes place and a agreed upon change or continuation takes place."

October 7, 2017 Response to Dr. Lembke's Helpful Analysis CVS Health and Opioids

I responded to this exchange with Dr. Lembke in part: "Your analysis was very helpful. I totally agree that physicians are unwittingly one of the major causes of the opioid abuse crisis and that if physicians and physician organizations were better at policing themselves, pharmacists would not need to. Thank you for your insight. It is helpful. I do agree that our intents and our commitments to finding a solution are the same. As a result of this discussion about CVS Health, the CDC Primary Guideline's for Opioid Us October 7, 2017 Response to Dr. Lembke's Helpful Analysis CVS Health and Opioids and your lectures, I met with our IT staff yesterday and we are deploying a support tool which automatically calculates the Morphine Milligrams Equivalent and prominently display it in several places in our EMR. All records which exceed 50 MME will be reviewed; all which exceed 90 MME will be referred to a SETMA specialist with special interest in this concern, and those unresponsive will be referred to a Pain Management Specialist. "

I added a section introducing the processes and ideas which have led SETMA to the point it is today.

CVS Health Dr. Lembke and Limiting Dispensing of Opioids to a Seven-Day Supply

This note of October 8, 2017 to Dr. Lembke resulted from further thoughts about CVS Health's plan to limit the dispensing of opioids to a one-week supply. In part I state:

"In conjunction with your last note, which expressed the value of only one week's supply of drug being dispense, I realized that you and I are both right.

- 1. If a PBM mail-order prescription, which limits dispensing to a one-week supply of an opioid at a time, can assure an uninterrupted delivery of medicine, the benefits you noted would be achieved, I.e., preventing patients "borrowing" drugs from next week's supply. The discipline would contribute to the decreasing of this method of abuse.
- 2. The problem will be that mail and other delivery methods are not dependable enough to make sure that the medication will predictably arrive every seven days. How many of us have paid significant additional fees to get next-day, or two-day delivery only to get delivery five or six days later? The additional anxiety and stress this will add to the life of people already living under great stress, will be accompanied with significant additional cost added to the obtaining of these medications. Who will pay that cost?
- 3. While CVS Health and their PBM, Care Mark, assures us that hospice and cancer patients will be excluded from their plan, how will CVS determine that the patient is on hospice or that they remain on hospice?
- 4. As my son's pharmacist friend affirms, our worst nightmare is real. If the patient is not receiving their medications by mail, with the problems that creates as detailed above, CVS Health's PBM plan will require the patient, the patient's family, or the patient's care giver to go to the pharmacy weekly. If that is a block away, it is problematical enough, but what if it is 25 miles away? Of course, CVS Health can provide an exemption, but who will administer that and how?"