

# **James L. Holly, M.D.**

## **CVS Health's Response to Dr. Holly Part I**

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**Your Life Your Health**

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On September 23, 2017, I wrote CVS's CEO, Larry Merlo, expressing my concerns about CVS' use of its Pharmacy Management Benefits (PBM) program to further intrude into healthcare. The following link is to that letter: [CVS Plans to Change Prescriptions without Physician Approval - An Open Letter to CVS' CEO](#). This letter also summarizes SETMA's extensive clinical tools for supporting the appropriate and safe prescribing of opioid medications including the electronic prescribing of controlled substances.

On September 28, 2017, I received a response from CVS Health's Executive Vice President and Chief Medical Officer. Below is that response and my observations.

**Caremark's CMO:** "Dr. Holly, I have attached a response to your concerns you sent along to Larry Merlo. After you have had a look, and if you still have questions, please be in touch with me."

**Dr. Holly's Response:** As apparent from the material above, I have graver concerns than I had before about receiving this explanation of CVS' plans.

**Caremark's CMO:** "Dear Dr. Holly, thank you for taking the time to share your views about our recent announcement regarding CVS Health's initiatives to fight the national epidemic of opioid abuse. As a leader in pharmacy care, we are dedicated to helping the communities we serve respond to this growing public health crisis."

**Dr. Holly's Response:** Two parts of this paragraph are bothersome. One is the use of the phrase, "epidemic of opioid abuse." The word "epidemic" traditionally was applied to infectious diseases. It has been being applied to behavioral problems such as obesity and now to opioid abuse. In some ways, the solutions to the opioid problem are obscured by calling it an "epidemic" rather than acknowledging that it is a behavioral, addictive problem. In some ways this use of the word has become a function of "political correctness" which tends to diminish the

individual responsibility for a problem of choice. One does not have to make a moral judgment about the behavior to acknowledge that it is a choice and to design a solution which includes personal responsibility.

The other problematical phrase in this paragraph is the term “pharmacy care.” This is a reflection of CVS Care Mart change of their name to “CVS Health,” which heralds the movement of CVS into the arena of Primary Care Healthcare Delivery and to the attempt to expand the role of pharmacists and pharmacies into the independent practice of healthcare.

**Caremark’s CMO:** “I think it is important to highlight that there are several components to our company’s efforts to help stem opioid abuse and misuse, including utilization management (UM) programs implemented through our pharmacy benefit manager (PBM), CVS Caremark, as well as education and support provided at our CVS Pharmacy retail locations. (CVS Caremark CMO.)

**Dr. Holly’s Response:** CVS Health inappropriately expands their legitimate function by the using of the concept of “utilization management.” Though their PBM, CVS Health is attempting to go beyond legitimate UM -- management of medication price negotiations, formulary management and number of pills prescribed for a specific period of time, i.e. if a patient takes one pill a day and receives 90 pills, a refill will not be authorized for 90 day -- to a third party PBM such as CVS Health determining the appropriateness of medication prescribing and the PBM controlling of the number of pills issued with a lawful prescriptions for a different amount. This is a usurpation of a legal action by a licensed provider which usurpation is completed by a pharmacist or a PBM who does not have the legal authority to take that action and who does not consult with the provider who wrote the prescription.

**Caremark’s CMO:** “Per our announcement, our PBM, CVS Caremark, will enhance our approach to opioid utilization management for all commercial, health plan, employer and Medicaid PBM clients as of February 1, 2018, unless the client chooses to opt out. This UM program will include a seven day limit on the supply of opioids dispensed for certain acute prescriptions for new-to-therapy patients; a limit on the daily dosage of opioids dispensed, based on the strength of the opioid; and a requirement to use immediate-release formulations of opioids before dispensing extended-release opioids. These limits are aligned with the [Guideline for opioid prescribing](#) issued by the Centers for Disease Control and Prevention (CDC) in 2016. With respect to the important role that the prescribing physician plays in the treatment of his or her patients, physicians are able to request an exception to the quantity limit based on their patient’s specific condition and medical need, as is possible with all of the treatment guidelines we implement through our PBM.”

**Dr. Holly’s Response:** CVS’ “enhancement” of their approach to opioid “utilization management” goes beyond the legal authority of a pharmacist which is the only legal authority a commercial enterprise such as CVS Health can take. In addition, CVS’ clever use of the “opt out” method makes it likely that most health plans will not recognize that to prevent CVS Health from taking this inappropriate and illegal action, the health plan must take the affirmative action of telling the PBM, i.e., CVS Health, that they are to act within the scope of their authority and not to take the proposed action. In most healthcare innovations, it has been determined that the “opt in” is the only legitimate course to take, but in that the actions proposed by CVS Health is inappropriate “opt in” or “opt out,” they are both equally inappropriate.

In the letter and *Health Affairs* blog below both of which are from the CVS Chief Medical Officer, it is candidly admitted that the “opt out” choice is being chosen as the standard in the expectation that many health plans will do nothing which will allow CVS Health to initiate their inappropriate and illegal action.

Later, this review will examine the CDC “Guideline for Opioid Prescribing” in detail. There is no question that SETMA agrees with the guideline. The problem we have is whether or not a PBM such as CVS Care Mart (CVS Health) has the legal or moral authority to enforce the guidelines. We are confident that CVS does not.

The subtlety and the insidiousness of the last sentence of this section is alarming; it states, “With respect to the important role that the prescribing physician plays in the treatment of his or her patients, physicians are able to request an exception to the quantity limit based on their patient’s specific condition and medical need, as is possible with all of the treatment guidelines we implement through our PBM.” The phrase, “the important role that the prescribing physician plays in the treatment,” drips with contempt by CVS for the legal ramification of healthcare professional licensure and privileges. Physicians, along with Nurse Practitioners and Physician Assistants play more than an “important role” in healthcare. They, in collaboration with patients and other members of the healthcare team including consulting pharmacists, play the key role. There is no role for CVS Health as a PBM in this process.

This last phrase of the above last sentence raises great alarms and motivates me to examine what other inappropriate utilization management strategies CVS Health has secretly or surreptitiously been employing in our patients’ healthcare decision making. The phrase states, “to the quantity limit based on their patient’s specific condition and medical need, as is possible with all of the treatment guidelines we implement through our PBM.” What other treatment guidelines has CVS Health implemented which allow pharmacists unilaterally to ignore physician orders?

**Caremark’s CMO:** “In our role as a PBM, CVS Caremark implements UM programs for a variety of prescription drugs in order to ensure the medications are clinically appropriate and cost effective. Given that this opioid UM program will be consistently executed as a coverage determination across all pharmacies in our PBM retail network, pharmacists at CVS Pharmacy, or any of the other retail pharmacies in our network, are not making independent medical judgments about the appropriateness of opioid prescribing or the length of such prescribing. Additionally, the program we have recently announced does not impact prescriptions filled for CVS Pharmacy retail customers who are not covered by the CVS Caremark PBM.”

**Dr. Holly’s Response:** The following statement which leads this paragraph is loaded with implications which require examination. “In our role as a PBM, CVS Caremark implements UM programs for a variety of prescription drugs in order to ensure the medications are clinically appropriate and cost effective.” In that CVS Health justifies its proposed usurpation of legal actions by physicians with illegal actions by CVS Health based on prior actions which may or may not have been legitimate, but which are now explained as their PBM’s determination of the “clinically appropriateness” of other drugs, it is imperative that all health plans and physicians working with them immediately learn what patient care judgments CVS Health has been making.

CVS argues that this new opioid UM program, “...will be consistently executed as a coverage determination across all pharmacies in our PBM retail network...” In this statement CVS Health

is being disingenuous. “A coverage determination,” means, one, that the drug is on the formulary and that if a three-month supply was issued three-months ago, a refill is covered.” The only legal “clinically appropriateness” which a PBM can enforce is that the patient has a diagnosis which supports the use of a medication. A pharmacist or a pharmacist organization (PBM) cannot legitimately question a diagnosis under its legal utilization management program.

**Caremark’s CMO:** “Separate from this UM program, our CVS Pharmacists will be strengthening counseling for all patients filling an opioid prescription in our stores, with a robust safe opioid use education program highlighting opioid safety and the dangers of addiction. This clinically-based program will help educate patients about the CDC Guideline, which advises the use of the lowest effective dose for the shortest duration possible. Our pharmacists will also counsel patients about the risk of dependence and addiction tied to the duration of opioid use, the importance of keeping medications secure in the home, and how to properly dispose of unused medication. To further support these efforts, we will also expand our Medication Disposal for Safer Communities Program to include a total of 1,550 safe disposal units, 750 of which will be located in CVS Pharmacy stores across the country.

**Dr. Holly Response:** There are parts of this paragraph which are problematical but none which are objectively illegal or unethical.

**Caremark’s CMO:** “We recognize that there are patients with a legitimate need for pain medication, and our approach is carefully designed to ensure that those patients can access their medication in an appropriate manner. We are dedicated to ensuring our retail- and PBM-based approaches do not negatively affect patients who, for example, have cancer or palliative care needs, and are in need of their medication to manage chronic pain.”

**Dr. Holly’s Response:** This is an appropriate caveat, if it is followed.

**Caremark CMO:** “Thank you again for taking the time to share your views and expertise.”