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CVS Health's Response to Dr. Holly Part II

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Your Life Your Health

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CVS Health Caremark continued the promotion of its plans regarding opioids in the prestigious *Health Affairs* September 21, 2017 edition in a blog co-authored by Caremark's Chief Medical Officer.

Caremark's CMO: "In the last two decades, prescribing rates for opioids have increased nearly three-fold, from 76 million prescriptions in 1991 to approximately 207 million prescriptions in 2013. This remarkable volume of opioid prescribing is unique to the United States, where 2015 prescribing amounts were nearly four times those in Europe. Sadly, this much more frequent prescribing of addictive medications is connected to an epidemic of deaths related to abuse of opiates and other drugs of abuse. Drug overdose deaths are now considered a national emergency, topping 59,000 in 2016. The abuse of opioids can be seen as the leading public health emergency in the United States faces today."

Dr/ Holly's response: I will not quibble with this statement, but I would argue that access to care, affordability of care, alcohol addiction, murder rates among minorities, abuse and/or neglect of the elderly, disparities of care and child abuse and hunger are also leading public health emergencies in this country. If the authors said that the abuse of opioids is "a" leading public health emergency in the US," it would solve this rhetorical deficiency in the blog.

The startling increase in the use of opioids has many causes. Two decades ago, health providers perceived that pain was under-treated, and in 1998 the Joint Commission formally recognized pain as the fifth vital sign. At the same time, drug companies developed and promoted a new generation of synthetic opioids, and added extended release as well as abuse deterrence formulations. Doctors prescribed, and patients consumed, these drugs in ever increasing quantities. At the same time, illicit forms of opioids became more widely available and abused. Now, with the harrowing increase in mortality attributed to opioid abuse, it is time to look for new solutions.

As the adverse consequences resulting from opioid misuse became apparent, employers sought the help of pharmacy benefit managers which responded by developing prospective (i.e., pre-dispensing) and retrospective utilization review programs to detect and intervene in unsafe prescribing of these addictive

medications. Patients and prescribers who were engaged in unsafe behavior were identified and educated. Other interventions, in the form of member-specific drug limits, dispensing restricted to a single pharmacy, and prior authorization to ensure use for an appropriate diagnosis, were implemented – all programs shown to reduce opioid abuse. These programs had positive effects, but the magnitude of the opioid epidemic continued to increase.

Seems self contradictory! These judgment is that these measures helped but evidence is that "the magnitude of the opioid epidemic continued to increase." None of these programs or processes interfered with the appropriate prescribing of medications but then CVS Health was not as brazen then as it has become since.

Caremark's CMO: "Pharmacy benefit management companies have still more aggressive utilization management techniques to guide physician prescribing, including such tools as quantity limits, step therapy to emphasize generics and restricted formularies. We believe these can be used to bring about more appropriate use of opiates for pain management. However, some prescribers may resist embracing recommended guidelines to address this epidemic at the broad population-level. The American Medical Association (AMA) for example has criticized such programs as heavy-handed, cookie-cutter approaches, and has counseled that providers should be making these decisions on behalf of patients, taking into account individual patient needs. To be sure, prescriber autonomy and respect for the physician-patient relationship are of paramount importance. However, there is little evidence to show that past opioid prescribing habits are necessary or appropriate, and there is a great deal of evidence that they have produced significant harm."

Dr. Holly's Response: I am not sure if I understand the last sentence in this paragraph. It appears to be rejecting the position of the AMA and physician-patient relationship or prescriber autonomy, but it is confusing. Perhaps the writers can explain what it means.

Caremark's CMO: "With widespread recognition that more aggressive control was called for, the Centers for Disease Control and Prevention (CDC) assumed the lead, announcing a Guideline for Prescribing Opioids for Chronic Pain in 2016. The CDC Guideline was based on three principles: opioids should be used only when necessary; only at the lowest dose and for the briefest duration needed; and when used, caution should be exercised and patients monitored closely. The Guideline made specific recommendations such as implementing step therapy requiring the use of immediate release formulations before extended release drugs when initiating treatment for chronic pain, avoiding doses greater than 90 Morphine Milligram Equivalents per day, and limiting prescriptions for acute pain to seven days or less. All of these recommendations can be integrated in standard utilization management."

Dr. Holly's Response: It is no oversight that the CDC calls their proposal "Guidelines," not "protocols." The Agency for Healthcare and Research and Quality's (AHRQ) published their National Guideline Clearinghouse which is described as "a public resource for summaries of evidence-based clinical practice guidelines." A "guideline" is an evidenced based recommendation, while a "protocol" is a rigid required step-by-step process analysis which must be followed.

What CVS Health calls "standard utilization management," most physicians would call "practicing medicine." My opinion is that the CDC Guideline should be implemented at the practice or provider level rather than at the PBM level. For physicians to monitor physicians and for physician committees

to establish "step programs" would be appropriate. For PBMs to disguise their practice of medicine in UM vocabulary is not.

Caremark's CMO: "How would implementing such recommendations affect patients and their employers? We have used commercial insurance data to estimate the impact that imposing limits on daily dosing and length of therapy as outlined by the CDC could have on opiate addiction. The evidence suggests that in a given year, at a company with 100,000 employees, 61 employees would avoid addiction if prescriptions were reduced to align with the doses and duration of use consistent with the CDC Guideline. For employers, this translates into substantial health care cost savings, as a person struggling with addiction would have more than $15,000 in additional health care costs a year as compared to a person who is not dealing with substance abuse. Perhaps more important is the incalculable avoidance of human suffering—as certainly any employer would want to prevent the pain and suffering experienced by employees and family members who have lost loved ones to the consequences of addiction."

Dr. Holly's Response: This paragraph is the most problematic from a science standard. The implementing of the recommendations in one practice will most often see patients just going to another practice where they can get what they want. The elimination of availability of medications at one venue has not resulted in a decrease in addiction. This is the most illogical paragraph in both Dr. Brennan's letter to me and in the Health Affairs blog.

Caremark's CMO: "In the face of such a crisis however, we believe it is time to give greater weight to the CDC Guideline — based on patient care and safety. The CDC Guideline should become the default approach to prescribing opiates, a scenario in which physicians would have to seek exceptions for those patients who need more medication or longer duration of therapy. What is more, pharmacy benefit managers are better placed than others in the pharmacy supply chain to put this approach to the CDC Guideline into practice. Wholesalers have no real contact with patients or payers. Retail pharmacists have opportunities to provide patient counseling about opiates, and are required by the Controlled Substance Act to exercise a "corresponding responsibility" as to whether a prescription was issued for legitimate medical purpose. But when faced with a valid prescription written by a medical professional, it is difficult, and often not appropriate, for retail pharmacists to take it upon themselves to limit prescribing."

Dr. Holly's Response: CVS Health is proposing the imposing of the CDC Guidelines in a coercive fashion by the PBM. This is consistent with the philosophy of many progressives and progressive organizations. It is not what the CDC Guidelines were intended, I think. If the CDC had proposed protocols, legislative or legal coercion may have been appropriate, but the CDC proposed "guidelines," which are not compulsory.

Caremark's CMO: "PBMs have experience with implementing and enforcing such efforts. Their adjudication systems can enforce quantity limits (both strength and duration) as well as ensure implementation of appropriate step therapy of immediate release formulations before more dangerous extended release opioids are used. Currently, the major PBMs all offer such programs to employers or insurers who "opt in" to the program. Greater gains are possible if PBMs make such programs automatic or "opt out." In this situation, clients would automatically have the limits built into their plan, unless they did not want them, and in standard PBM practice, few clients tend to opt out."

Dr. Holly's Response: There is no correlation between the prescribing of an excessive dosage of a medication where an objective, evidenced-based standard exists in the medical literature and the refusal to fill a legal prescription by a legal provider. For instance, if a provider prescribes 160 mgs of Atorvastatin, it could legitimately be rejected as it is objectively a toxic dose.

That is not what CVS Health is proposing for opioids. CVS Health is declaring that in order to control the abuse of these medications, an obviously ineffective way will be employed, which supposedly will made successful simply by making it more difficult to obtain the opiods. That is UM gone amuck and it not a strategy which is likely to success. As evidence one simply has to see the extremes to which people are willing ot go to obtain illegal drugs, or to illegally obtain legal drugs.

Caremark's CMO: "In the end though, preventing opiate addictions and deaths are one of the core health benefits that payers, employers and insurers, should provide to employees and members. In light of the human suffering and financial costs caused by the current epidemic, a thoughtful, responsible, evidence-based treatment of pain is a service we must provide to our patients. Employing principles sanctioned by the CDC is clearly necessary and prudent."

Dr. Holly's Response: There is nothing in the CDC Guidelines which promotes for or allows pharmacists, or PBMs to violate the laws of the states in which they operate.

The statement which identifies "core health benefits that payers, employers and insurers…" shows the misplaced values of this effort to impose care upon people who don't want care. Is this effort about public health or is it about profit of companies?

The bottom line for me in this entire discussion as a primary healthcare provider is that I want to continue to work every day, as I have for the past forty-four years, to help people make the right health care decisions, while being fully aware they have the right to make bad decisions. Ultimately, I have the responsibility not to facilitate, or to participate in their bad decisions.

Confronted with CVS Health's proposal, many, if not most, people who are addicted to prescription drugs will make the same decision that one of my patients made years ago. When I saw her she was enormously overweight, at 5 feet tall, she weighed over 450 pounds. After a careful dietary history, I was convinced that she consumed about 1700 calories a day. I asked her, "Do you drink cokes?" She answered, "No," to that and to tea. When I asked about coffee, she admitted that she drank over 40 cups of coffee a day. Before you express incredulity, I once had a patient in residency that drank five cases of beer a day.

When I asked what she put in her coffee, she said that she used two teaspoons of sugar and one tablespoon of fresh cow cream. I talked to her about changing her habits and offered help and encouragement. Pleased that I had practice good, patient-centered care, I was not surprised at her decision.

She changed doctors.

Compulsive and addictive behavior is compulsive and addictive. All the PBMs utilization management will not change that. Even compassion and counseling will not always change it.