



March 16, 2018

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: FDA-2017-N-6502; Opioid Policy Steering Committee: Prescribing Intervention--Exploring a Strategy for Implementation; Public Hearing; Request for Comments

Submitted electronically via <http://www.regulations.gov>

Dear Commissioner Gottlieb,

Trinity Health appreciates the opportunity to comment on the proposed interventions laid out in the Opioid Policy Steering Committee's Prescribing Intervention Request for Comment (FDA-2017-N-6502). Our comments and recommendations to the Food and Drug Administration (FDA) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health strongly believes that health systems and hospitals must play a critical role in addressing opioid use and misuse. Trinity Health is committed to developing and implementing important opioid utilization reduction strategies, ensuring comprehensive education and awareness programs, engaging in robust advocacy, and measuring impact to ensure continuous improvement for all populations that we serve. Committed to putting the people and communities we serve at the center of every behavior, action and decision, Trinity Health is broadly collaborating—through our Opioid Utilization Reduction (OUR) initiative—for the system-wide development, evaluation and dissemination of evidence-based tools and protocols for optimizing care and reducing opioid harm.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Trinity Health includes 93 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns \$1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with Graduate Medical Education (GME) programs providing training for 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

Trinity Health believes that altering the course of opioid use and misuse must include the following imperatives that encompass prevention, intervention, treatment and recovery:

- Building awareness, education and engagement across all stakeholders including patients, providers, pharmacists, families and communities. Broad community education is critical.

- Ensuring resources and coordinated, comprehensive solutions across local, state and federal levels of government.
- Supporting a whole-person approach to meet the full range of an individual's physical, behavioral and social support needs in an integrated fashion and recognizing that each of these dimensions impacts a patient's experience of pain as well as his/her health and wellness.
- Enhancing prevention through communication, transparency and accountability among all stakeholders.
- Breaking down barriers to effective treatment and recovery including reducing stigma and ensuring appropriate insurance coverage.

We appreciate the ongoing work of the FDA's Opioid Policy Steering Committee as it is aligned with many of the above outlined imperatives. As FDA's efforts continue, we bring the following important considerations to the attention of the Committee.

First, Trinity Health's OUR initiative has identified prescriber education as the most critical need for our hospitals and clinicians to be successful with reducing opioid utilization and related harm. While we support increased prescriber education initiatives, we also have concerns that the varying requirements coming from local, state and federal entities is quickly becoming confusing. **Ensuring that government mitigation measures – including provider education requirements – are not duplicative in nature and are as consistent as possible across all states is critically important to avoiding confusion and undue burden on providers.**

Trinity Health strongly believes that providing prescribers with resources and education about national guidelines for safe and appropriate opioid prescribing is the foundation for opioid utilization reduction education. We support wide dissemination of the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain. Additionally, across the entire Trinity Health system, two critical prescriber education platforms are being rolled out – first is the SCOPE of Pain for basic overview training and secondly is the Center to Advance Palliative Care (CAPC) for pain management competency based training. Supporting advancement of responsible, evidence-based opioid prescribing and counseling through pain management education, safe prescribing training, and addiction training for all prescribers and dispensers throughout medical schooling and beyond is critical. **Trinity Health urges the FDA to work with other agencies within the Department of Health and Human Services (HHS) to avoid duplication; and, additionally urges consideration of the above referenced educational resources as applicable.**

Secondly, it is critical to recognize the importance of ensuring that the pendulum not swing too far in the other direction. We strongly urge that public policies intended to reduce inappropriate use of opioids do not simultaneously create access barriers to pain management for patients for whom opioids are medically indicated and who are benefiting from such treatment.

While Trinity Health supports and, as stated earlier, is widely disseminating the CDC Guidelines. **It is important that these clinical guidelines not be narrowly interpreted into overly restrictive policy and across-the-board requirements that could result in numerous negative, unintended consequences.** For example, the CDC states: "*This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.*" **Trinity Health strongly urges that public policies – including those advanced by the FDA – to address inappropriate opioid use should always include exceptions for hospice care, cancer diagnoses, end-of-life care, and palliative care.** Many institutions and payers are establishing dose and time limits for all patients, irrespective of their underlying diagnosis or context or goals. Again, public policies must not be so overly restrictive that it inhibits clinical decision-making on the needs and circumstances of individual patients.

Thirdly, we appreciate and support FDA's desire for a nationwide prescription database, and urge that existing infrastructures be leveraged, simplified and strengthened to achieve this goal rather than creating another layer of technology. Prescription Drug Monitoring Programs or PDMPs hold great promise as demonstrated by the recent *Health Affairs* study, which found that both the number of opioid prescriptions and spending was significantly lower in states with a registration mandate or a registration and use mandate, compared to states without either. For example, opioid prescriptions declined 28 percent in Massachusetts from 2015 to 2017 with 97 percent of health care providers registered with their awareness tool that's getting an average of 125,000 searches a week. And the Ohio database processed more than 24 million queries from physicians and other health professionals in 2016 while the number of opioids dispensed to Ohio patients decreased 20 percent since 2013.

Investments must be made in innovative technology that advances interoperable, interstate data-sharing nationwide. Strengthening utilization and connectivity between PDMPs and electronic health records (EHRs) is a very important component of the ability to achieve functional and efficient interstate data-sharing. As a national health system operating in 22 states, we are proactively mapping out a system-wide strategy to ensure our EHRs are able to capture states' PDMP data to make the process as seamless as possible for providers. Ensuring national, cross-state exchange of information is critical. **We urge FDA to ensure that database efforts advanced by the agency – including related requirements on providers – not be overly burdensome and are integrated into existing databases, systems and workflow.**

Fourthly, we appreciate the FDA's acknowledgement that improvements need to be made towards the safety of patient storage and handling of opioids and expanded opportunities for safe disposal of opioids including the role of sponsors in broadening access to these disposal options. As part of Trinity Health's Patient Discharge Instructions entitled "What You Should Know About Opioid Medicine" (*attached to this letter*), we offer patients key information on how they can safely store and dispose of their opioids. **The FDA should explore how the agency could support an increase in the number of and access to permanent prescription take-back programs and drop-off sites as well as broadening access to disposal options such as drug deactivation systems.**

Lastly, Trinity Health strongly supports expanded options for non-opioid and non-pharmacological alternative approaches to pain management. The FDA has an important role in supporting this research and speeding these alternatives to market. More comprehensive utilization of these modalities have great potential to reduce opioid use and improve patient functionality and outcomes.

We appreciate the FDA's commitment to exploring strategies that best address the opioid crisis facing our nation. If you have any questions on our comments, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,



Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health

ATTACHMENT TO THESE COMMENTS:

Trinity Health's Patient Discharge Instructions entitled "What You Should Know About Opioid Medicine"

What You Should Know About Opioid Medicine

What is an Opioid?

Opioid medications **are used to treat moderate to severe pain**. Morphine, Oxycodone (Percocet®), Hydromorphone (Dilaudid®) and Hydrocodone (Norco®) are some types of opioids.

How do Opioids work?

Opioids reduce the pain signals sent to your brain, which decrease your feelings of pain. Opioids may reduce your pain, but may not take all the pain away.

What are the risks from taking opioids?

Prescription opioids carry serious risks of physical dependence, addiction and overdose, with long term use. **If you take too much of an opioid it can cause sudden death.**

Other risks include but are not limited to:

- **Physical dependence** means you have symptoms of withdrawal when a medication is stopped.
- **Addiction** is a brain disease. Medications change the structure of the brain and how the brain works. These brain changes may be long lasting and can lead to harmful behaviors.
- **Overdose** means you took too much medication. Opioid overdose can result in death.

Make sure you read all of the medication sheet you received with your prescription.

Call 911 right away if you have any of these signs of overdose:

- Pale or bluish skin color
- Trouble breathing
- Severe confusion; not knowing where you are
- Your heart is beating slower than normal
- You see or hear things that are not real

Tell the people you live with that you are taking a medicine that can stop your breathing. Ask them to watch for slow, shallow, or trouble breathing. **Tell them to call 911 right away if you have trouble breathing or they cannot wake you up.**

What you need to know while taking Opioid medication:

- **Do Not** take more medication, or higher doses than prescribed, as you may stop breathing or pass out.
- **Do not take opioids more often or in higher doses than prescribed. Call your doctor if your pain is not controlled.**
- **Do Not** drink alcohol (beer, wine or liquor) while taking this medication, as you may stop breathing or pass out.
- **Do Not** take sleeping pills (like zolpidem (Ambien®) or temazepam (Restoril®) or anti-anxiety medication (like alprazolam (Xanax®), diazepam (Valium®), and lorazepam (Ativan®) while taking this medication, as you may stop breathing or pass out.
- **Do Not crush or alter opioid medication or take it in ways not prescribed by your doctor**
- **Do not** drive or do tasks that require you to be alert after taking this medication.
- **If you are pregnant, talk to your doctor. Opioids may harm your pregnancy or baby.**

What are the side effects from taking opioids?

The most common side effects are:

- Hard stools (Constipation)
- Upset stomach, throwing up and dry mouth
- Feeling sleepy

- Feeling more pain
- Confusion
- Depression, low mood, feeling sad or nervous
- Itching and sweating
- Trouble passing urine

Will I become addicted to opioid medication?

Addiction is not common when this medication is used for a short time. But, when opioid medications are misused addiction is possible. Talk with your doctor about how to switch to using only non-opioid pain treatment. Please talk to your doctor about your concerns about addiction.

How do I safely store and dispose of my opioids?

Storage:

- Keep your medications secure.
- Keep your medications, including any medication patches, out of reach of others (this includes children, friends, family and pets).
- Keep your opioids, and all medications, in the pill bottle from the pharmacy. Keep the lid closed.

Disposal:

- Safely throw out unused opioids: Contact your local pharmacy for how to throw out unused opioid medications or find your local medicine take-back site (<http://disposemy meds.org/>)
- Follow these steps if you can't find a medicine take-back site to throw out expired, unused or unwanted medicines:
 - Step #1: Mix medicine with used coffee grounds, dirt, or kitty litter.
 - Step #2: Put medicines in a sealed plastic bag.
 - Step #3: Place plastic bag in the trash.
 - Step #4: Take prescription bottle and scratch out personal information, then recycle or throw away.
- Throw out patch medications by folding them in half with the sticky sides together, and then flushing them down a toilet. Do not place them in the household trash where children or pets can find them.

It is against the law to share or sell your opioid medication.

What else can I use to treat my pain?

Non-opioid pain medications (such as Tylenol®, Motrin®, and Aleve®) may also help with your pain. If your doctor approves, these medications may be used with an opioid medication ordered for you. Non-opioid pain medications also have risks and side effects; please ask your doctor if these medications are safe for you.

Many opioid medications also have acetaminophen (Tylenol®) in it. Very bad, and sometimes deadly, liver problems can happen with too much acetaminophen use.

What are other ways to help ease your pain?

- Heat or ice
- Stretching
- A pillow under the painful area
- Massage
- Talking to someone about how your thoughts and feelings affect your pain
- Listening to music

Talk to your doctor to make sure these actions are safe for you