Trinity Health

March 15, 2018

The Honorable Kevin Brady
Chairman
Committee on Ways & Means

The Honorable Richard Neal
Ranking Member
Committee on Ways & Means

The Honorable Peter Roskam
Chairman
Subcommittee on Health

The Honorable Sander Levin
Ranking Member
Subcommittee on Health

Re: House Committee on Ways and Means Opioid and Substance Use Disorder Policy Questions

Submitted electronically to WMOpioidSubmissions@mail.house.gov

Dear Chairmen Brady and Roskam and Ranking Members Neal and Levin,

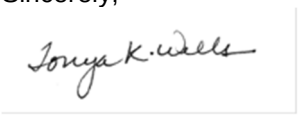
Trinity Health appreciates the opportunity to comment on the policy questions you have laid out as the Committee considers ways in which it can address the devastating impact of the opioid crisis. Our recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. We also believe that reverence – honoring the sacredness and dignity of every person – is inherently necessary to reducing opioid harm.

We strongly believe 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.

We appreciate the Committee's commitment to exploring strategies that best address the opioid crisis facing our nation. If you have any questions on our comments that follow, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824. We look forward to closely working with you as the Committee develops a legislative package on this issue. We would greatly welcome the opportunity for our subject matter and clinical leaders to sit down with you and share more of our experiences and positions on this incredibly important issue impacting all of our communities.

Sincerely,



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

Trinity Health is committed to partnering with all stakeholders to address opioid use through prevention, intervention, treatment, and recovery initiatives. As we work to address the country's culture of pain, we must also recognize that a patient's experience of pain depends on many factors including comorbidities, stress levels, and social supports. Trinity Health strongly believes that altering the course of opioid and substance use disorders 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.

While many state legislatures have enacted targeted measures to address the opioid crisis, **a coordinated nationwide strategy that prioritizes appropriation of federal funding for programs to support the opioid efforts of state and local governments, hospitals, and community-based organizations is required. Ensuring that federal and state mitigation measures and provider education requirements or initiatives are as consistent as possible across all states to avoid duplication, confusion, and undue burden on providers is of critical importance.**

OVERPRESCRIBING AND DATA TRACKING

Prescribing Guidelines and Requirements
It is critical that policymakers acknowledge and recognize the importance of ensuring that the pendulum not swing too far in the other direction as we collectively work to reduce opioid misuse and abuse. **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 discussed later in these comments, is widely disseminating the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain, 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 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, 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.

We also have significant concerns with the proposed 3-day limit on initial opioid prescriptions for acute pain in the CARA 2.0 package introduced in the Senate. A 3-day limit is overly restrictive public policy, as it inhibits clinical decision-making based on the needs and circumstances of individual patients and could cause significant harm for surgery patients in particular. Patients with legitimate pain needs could be left on a weekend, for example, without the availability of a clinician to provide additionally needed days of a prescription to treat their pain. **Limiting the initial supply of an opioid prescription for acute pain to 7-days is a more reasonable approach to addressing the reservoir of unused prescription opioids, and less problematic for clinical decisions based on individual patient's circumstances and needs.** The CDC states: "*When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.*" CDC's clinical guidelines acknowledge that three days is often sufficient but not always. Limiting to 3-days could also encourage prescribers to write second and third prescriptions to be used at a later date which could further exacerbate the problems surrounding opioid misuse and abuse.

To ensure that the pendulum not swing too far in the other direction and create access barriers to pain management for patients for whom opioids are medically indicated, **we would also support funding to improve the pain management evidence base.** This could, for example, support a supplement to the CDC Guidelines that provides greater direction beyond the primary care audience for which these Guidelines were originally intended.

Improving PDMP Utility

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.

However, it is critical that policymakers address inadequate databases and ensure cross-state information exchange. This is particularly important for providers that practice near borders and have patients coming from a neighboring state to seek care. **Additional investments should be made in innovative technology that advances interoperability and interstate data-sharing among PDMPs nationally.** As a national health system operating in 22 states, we are proactively mapping out a system-wide strategy to ensure our electronic health records (EHRs) are able to capture states' PDMP data to make the process as seamless as possible for providers. Ensuring cross-state exchange of information and active alert systems are critical next steps. **We also urge that these database efforts – including related requirements on providers – not be overly burdensome and are integrated into these existing databases, systems and workflow.**

COMMUNICATION AND EDUCATION

Provider Education

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 CDC Guidelines. 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 to policymaking. Additionally, Trinity Health has developed – and integrated into our electronic health record (EHR) – the attached, two-page opioid discharge education piece for patients. **If the Department of Health and Human Services (HHS), including Medicare and Medicaid, were directed to coordinate the development of a national curriculum and standard of care for opioid prescribers, we strongly urge that all of the above referenced educational resources be utilized. We also urge that the Committee prioritize education requirements that are as consistent as possible across all states to avoid duplication, confusion, and undue burden on providers.**

TREATMENT

Access to Non-Opioid and Non-Pharmacological Alternative Approaches to Pain Management

Across Trinity Health's continuum of care providers, we daily hear of struggles associated with coverage and access to non-opioid and non-pharmacological alternative approaches to pain management. **Meaningful coverage – from both Centers for Medicare and Medicaid Services (CMS) and third-party payers – to non-opioid and non-pharmacologic alternatives is one of the most important long-term strategies policymakers can address to combat the opioid crisis facing our nation. The Food and Drug Administration (FDA) also has an important role in supporting research into these alternatives and speeding alternatives and approvals to market.** More comprehensive utilization of these modalities have great potential to reduce opioid use and improve patient functionality and outcomes.

As an example of non-opioid alternatives, Lyrica (pregabalin) is an extremely valuable medication in treating numerous neuropathic pain syndromes but has only been approved for minimal indications, such as fibromyalgia. This non-opioid medication is extremely effective for treating several neuropathic pain syndromes, but it is very difficult for a patient to garner approval for its use. Additionally, utilizing procedures – for example injections such as epidural steroids that can be used to treat acute exacerbations of radicular pain – is another critical example to reducing opioid use in patients. Coverage for these procedures, however, are increasingly being denied. Non-pharmacological alternatives – such as physical therapy and cognitive behavioral therapy – as well as complementary approaches – such as acupuncture and chiropractic therapy – are also critical. More comprehensive utilization of these alternative approaches is paramount to minimizing the risk that people develop opioid or other substance use disorders. **Ensuring access to and low or no co-payments for non-opioid and non-pharmacological pain management modalities could reduce opioid misuse and improve patient functionality and outcomes.**

Current CMS reimbursement policies, as well as those from other health insurance payers, create barriers to the adoption of these alternative strategies. This is a significant barrier in clinicians being able to consistently and more broadly embrace utilization of these alternative and complementary pain management approaches. **We strongly urge that a broader range of pain management and treatment services – including alternatives to opioids, physical therapy, cognitive behavioral therapy, acupuncture, and chiropractic therapy – be adequately reimbursed by payers, including Medicare and Medicaid. Specifically, CMS should review and modify rate-setting policies that discourage the use of non-opioid treatments for pain.**

Coverage and Access to Treatment

Breaking down barriers to effective prevention, screening and treatment is critical, and any opioid reduction strategy must be accompanied by increases in access to treatment. According to the National Institute on Drug Abuse (NIDA), every dollar invested in addiction treatment yields a return of up to $7 in reduced drug-related crime and criminal justice costs. When health care savings are included, the return on investment can exceed $12. **CMS must ensure meaningful insurance coverage of and access to evidence-based medication-assisted treatment (MAT) for opioid use disorder. This includes limiting prior authorization requirements and ensuring there are no lifetime limits and no arbitrarily low dose and time limits for treatment of these patients in order to effectively improve patient outcomes.** Significant access challenges also result from having too few providers certified to prescribe these medications, such as Buprenorphine, as well as the costs of these medications often prohibiting access as well. **Congress should appropriate funding to expand MAT training and provide financial incentives for prescribers willing to secure waivers to prescribe Buprenorphine.**

The impact of opioid use disorders impacts all age groups and demographics. **Eliminating the restriction on Medicaid payments for inpatient treatment at large residential facilities (i.e., the Institutions for Mental Diseases (IMD) exclusion) is important to expanding treatment for those covered by Medicaid. For those covered by Medicare, it's important that Methadone treatment be covered not just in the inpatient setting but in the outpatient setting as well.**

Supporting a Team-Based Workforce

A critical component of ensuring that all individuals receive the best, evidence-based prevention, screening, and assessment is an effective workforce. **We urge CMS to provide appropriate reimbursement and financial incentives for supporting a collaborative, team-based environment that includes psychiatrists, addiction medicine specialists, advance practice clinicians (e.g., PAs, NPs), psychologists, social workers, nurses, care coordinators, community health workers (CHWs), and peer-to-peer support specialists.** Allowing these individuals to practice at the highest level of their education, training and licensure is also important.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act of 2008 built on the Mental Health Parity Act of 1996 by requiring that coverage provide the same level of benefits for substance use and mental health as it does for other medical care. While parity is a requirement, enforcement remains a challenge. **Parity regulations must be adequately and uniformly enforced for these policies to be effective and to ensure evidence-based, coordinated care is received for those with opioid and substance use disorders. CMS has an important role in this imperative. We also urge the Committee to examine additional ways to ensure all beneficiaries of federal health programs are benefiting from mental health parity and treated equitably relative to commercial and managed care plans.**

42 CFR Part 2

Critical to advancing effective prevention, screening and treatment efforts is also for Congress to align confidentiality requirements for sharing a patient's substance use disorder records (known as 42 CFR Part 2) with the requirements in the Health Insurance Portability and Accountability Act (HIPAA) so that opioid and substance use disorders can be treated like other medical conditions, improving patient safety and continuity of care. **Aligning the confidentiality of substance use records with HIPAA requirements – thereby granting health care providers access to information to diagnose and effectively treat patients who use opioids and other controlled substances – will better ensure integrated care across providers and settings.** As a result of these antiquated regulations, opioid and substance use disorder diagnosis and treatment information gets locked away from other providers and care managers, fueling bifurcation, limiting care coordination, and creating safety risks for beneficiaries. **Specifically, we urge Congress to include the Jessica Grubbs Legacy Act (S.1850)/the Overdose Prevention and Patient Safety Act (H.R. 3545) in any opioid-related package.**

ATTACHMENT TO THESE COMMENTS: Trinity Health's Patient Discharge Instructions on Opioids

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://disposemymeds.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 <u>against the law</u> 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.