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Memorandum

Date: April 9, 2018

From: Holland & Knight

To: Interested Healthcare & Life Sciences Clients

Re: Opioid Crisis Proposals and Funding

Opioid Funding Overview

In 2016, through the *Comprehensive Addiction and Recovery Act* (CARA) and the *21st Century Cures Act*, Congress authorized roughly \$1.4 billion in spending to combat the opioid crisis. Specifically, the Cures Act awarded \$500 million in grants to states for both Fiscal Year (FY) 2017 and FY 2018 to supplement their efforts addressing opioid abuse. However, funding for provisions of CARA and for the FY 2018 state opioid grants under the *21st Century Cures Act* were not secured and subject to the FY 2018 appropriations bill.

Building on the funding provided through CARA and the Cures Act, Congress passed the *Bipartisan Budget Act of 2018* on Feb. 9, 2018. The bill authorizes \$6 billion to address the opioid crisis and improve mental health care — with \$3 billion for FY 2018 and \$3 billion for FY 2019. Funds are intended to enhance state grants, prevention programs, and law enforcement activities related to substance use and mental health programs.

The opioid funding for FY 2018 under the *Bipartisan Budget Act* was appropriated in the FY 2018 omnibus appropriations bill. The FY 2018 appropriations bill allocated more than \$4.65 billion across agencies to help states and local governments in their efforts toward prevention, treatment and law enforcement initiatives. That represents a \$3 billion increase over 2017 spending levels.

The *Bipartisan Budget Act* opioid funding for FY 2019 is still subject to the FY 2019 appropriations process. Planning for the FY 2019 budget, which goes into effect on Oct. 1, 2018, has already begun at the agency level. We anticipate FY 2019 funding levels for opioid treatment to be retained, if not increased.

The FY 2018 omnibus appropriations bill, as noted above, included funding authorized under the *21st Century Cures Act* and CARA, as well as additional funding for opioid-addiction and mental health services.

The FY 2018 funding breakdown was very high-level and included:

- \$500 million to supplement the State Targeted Response to the Opioid Crisis grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) and authorized under the *21st Century Cures Act*
- \$330 million for law enforcement grant programs, including those authorized under CARA and:
 - \$75 million for drug courts
 - \$30 million for mental health courts and adult and juvenile collaboration program grants
 - \$30 million for Residential Substance Abuse Treatment for State Prisoners grants
 - \$20 million for veterans treatment courts program
 - \$30 million for prescription drug and scheduled chemical products monitoring
 - \$145 million for a comprehensive opioid abuse program
- \$500 million for the National Institutes of Health (NIH), including money for researching non-addictive pain relief options;
- \$476 million within the Centers for Disease Control and Prevention (CDC) to combat the opioid crisis, including funding for state Prescription Drug Monitoring Programs (PDMPs) and activities within the National All Schedules Prescription Electronic Reporting system.
- \$100 million for the Rural Communities Opioid Response, which would include direction to "increase use of telehealth"; \$30 million of this would be derived from the National Health Service Corps (NHSC), which saw a \$105 million boost over the FY 2017 level
- \$84 million provided specifically to promote medication-assisted treatment for prescription drug and opioid addiction

Prior to the passage of the omnibus and after the budget agreement, President Donald Trump released the FY 2019 budget proposal detailing his Administration's legislative and regulatory priorities for next year, and he highlighted combating opioid misuse, abuse, and overdose as a key priority. In addition to the budget itself, the Office of Management and Budget (OMB) issued an addendum that reflects the higher non-defense discretionary (NDD) spending caps from the Budget Act.

The budget proposed \$10 billion in new U.S. Department of Health and Human Services (HHS) funding for programs related to opioid abuse. The addendum would provide an additional \$5 billion for HHS to address the opioid epidemic and serious mental illness. Of the \$10 billion request, only \$3 billion has been allocated to specific agencies within HHS. Another \$7 billion would be appropriated to an account within the Office of the Secretary of HHS, which would then have discretion in how to distribute those amounts across the Department. There is funding that is above the caps set by the Bipartisan Budget Act and would therefore require Congressional approval.

The funding would be directed towards investments to advance HHS' five-part opioid strategy, which involves:

1. Improving access to prevention, treatment and recovery services, including medication assisted therapies
2. Targeting availability and distribution of overdose-reversing drugs
3. Strengthening our understanding of the epidemic through better public health data and reporting
4. Supporting cutting edge research on pain and addition
5. Advancing better practices for pain management

The budget also proposed to test and expand a nationwide Medicare bundled payment for community-based medication assisted treatment (including reimbursement for methadone treatment), prevent

prescription drug abuse in Medicare Part D and revoke a provider's controlled substance prescribing certificate when there is a pattern of abusive prescribing.

Notably, HHS Secretary Alex Azar pledged to expand the use of medication-assisted treatment (MAT) to treat opioid addiction. In addition, the budget calls for Medicare and Medicaid to cover all therapies associated with substance overuse and abuse, including needed counseling services.

Following passage of the aforementioned budget deal and FY 2018 appropriations legislation, Congress is hurrying to identify policies that could fit into this funding framework.

Most major actions to date have been taken by the House Energy and Commerce Committee as well as the Senate Health, Education, Labor and Pensions (HELP) Committee, including multiple hearings by both committees on a wide range of issues related to the opioid epidemic. While these committees have considered more than 50 pieces of legislation related to the opioid epidemic, this list is not exhaustive and there remain many other bills that could potentially be included in a final opioid package. Although details remain limited, the overall goal is to roll these bills into a package along with CARA 2.0 proposals to be considered and passed before Memorial Day 2018.

The timing of the package is dependent on receiving technical assistance from the various agencies that have jurisdiction over applicable provisions in these bills. Given nearly universal support for combating the opioid epidemic, many are assuming that this package will still be able to move despite the typical legislative standstill that occurs before midterm elections. Congressional leaders maintain that this effort will remain bipartisan, thus precluding more controversial measures from being included in the final package.

Below is an overview of funding and legislative proposals to address the opioid epidemic. Please note that this is not an exhaustive list of current or potential funding opportunities across all federal agencies.

Opioid House Proposals Overview

CARA 2.0

In the House, a bipartisan group introduced [legislation](#) to address the epidemic, framing it as a follow-up bill to CARA, which was signed into law in 2016. Dubbed CARA 2.0 (H.R. 5311), the legislation includes a host of policy changes, such as establishing a three-day initial prescribing limit on opioids for acute pain, beefing up services to promote recovery and aiming to increase the availability of treatment. CARA 2.0 would also allow states to waive the number of patients a physician can treat with buprenorphine.

The current version of the bill increases funding authorization levels to coincide with the recent budget agreement and lays out new policy reforms to strengthen the federal government's response to the crisis. The bill authorizes \$1 billion in additional funding, which includes \$10 million for a national education campaign, \$300 million to expand access to medication-assisted treatment (MAT), \$200 million to build a national infrastructure for recovery support services, and \$300 million for expanding first responder training and access to naloxone.

Sponsors include Reps. Ann Kuster (D-N.H.), Marsha Blackburn (R-Tenn.), Tim Ryan (D-Ohio), and Tom MacArthur (R-N.J.).

House Ways and Means Proposals

The House Ways and Means Committee requested information from insurers, pharmacy benefit managers (PBMs), and healthcare providers and prescribers about how to better protect Medicare beneficiaries from opioid dependence and overdose. The Committee is currently drafting its own bipartisan opioid-related legislation and is looking to leverage Medicare to combat opioid abuse and addiction. The lawmakers requested feedback by March 15 related to overprescribing, data tracking, communication and education, and expanding treatment options in Medicare.

House Energy and Commerce Committee Action

The House Energy and Commerce Committee's Subcommittee on Health has held two of three total legislative hearings in 2018 to examine the opioid crisis and possible solutions related to the Controlled Substances Act. To date, the first two hearings, held on Feb. 28 and March 20-21, respectively, focused on the balance between enforcement and patient safety. As mentioned above, Committee Chairman Greg Walden (R-Ore.) hopes to pass legislation related to the opioid epidemic in the House before Memorial Day weekend.

The Subcommittee will hold the third of three legislative hearings on the opioid crisis on Wednesday, April 11, 2018, beginning at 2:15 p.m. The hearing is entitled, "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients."

The Chairman's press release for the third hearing lists 34 bills for consideration, including: 1) Medicaid legislation regarding benefits and services, lock-in programs, covered prescription drug utilization review, Prescription Drug Monitoring Programs (PDMPs), provider training, treatment for infants with neonatal abstinence syndrome and mental health parity; 2) Medicare Part B policies, including payment to encourage development of non-opioid drugs, use of telehealth to treat opioid use disorder, alternative payment models for substance use disorder treatment and incentives for use of post-surgical injections as a pain treatment alternative to opioids; and 3) Medicare Part D policies, including electronic prescribing for controlled substances, drug management programs for at-risk beneficiaries, standardized electronic prior authorization, beneficiary education, use of abuse-deterrent opioids, determinations/notification of outlier opioid prescribers, prescriber education and expansion of medication therapy management programs.

A [grid of all bills](#) that have been and will be considered by the House Energy and Commerce Committee in the context of its opioid hearings may be found on Holland & Knight's website.

Opioid Senate Proposals Overview

Senate Health, Education, Labor and Pensions (HELP) Committee Proposals

Committee leaders announced they will hold a hearing on the Senate HELP Committee's draft bill, titled the *Opioid Crisis Response Act of 2018*, on April 11, the same day that the House Energy and Commerce Committee is holding its final hearing on opioid legislation. The House aims to pass a bill ahead of Memorial Day, while the Senate hasn't stated a deadline but has held six other hearings on the issue.

The *Opioid Crisis Response Act of 2018* will:

- Spur development of non-addictive painkillers and other strategies to prevent, treat, and manage pain and substance use disorders through additional flexibility for the NIH and clarifying guidance from the U.S. Food and Drug Administration (FDA)
- Encourage responsible prescribing behavior by clarifying FDA authority to require packaging options for certain drugs, such as opioids to allow a set treatment duration, e.g., "blister packs," for patients who may only need a three-day or seven-day supply of opioids (*FDA Commissioner Scott Gottlieb has already expressed support for the use of pre-formed plastic packaging as a means to curb new addictions*)
- Clarify FDA authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids
- Improve detection and seizure of illegal drugs, such as fentanyl, through stronger FDA and Customer Border Protection coordination
- Clarify FDA's development and regulatory pathways for medical product manufacturers through guidance for new non-addictive and non-opioid pain products
- Provide support for states to improve their PDMPs and encourage data sharing between states so doctors and pharmacies can know if patients have a history of substance misuse
- Strengthen the healthcare workforce to increase access to mental health services in schools and to substance use disorder treatment in underserved areas
- Authorize CDC's work to combat the opioid crisis, including providing grants for states, localities and tribes to collect data and implement key prevention strategies
- Address the effects of the opioids crisis on infants, children and families, including by helping states improve plans of safe care for infants born with neonatal abstinence syndrome and helping to address child and youth trauma
- Authorize the U.S. Department of Labor to address the economic and workforce impacts for communities affected by the opioid crisis, through grants targeted at workforce shortages for the substance use and mental health treatment workforce, and to align job training and treatment services
- Update U.S. Drug Enforcement Administration (DEA) regulations to improve treatment access for patients in rural and underserved areas through telemedicine, while maintaining proper safeguards
- Allow hospice programs to safely and properly dispose of unneeded controlled substances to help reduce the risk of diversion and misuse

The text of the [discussion draft](#) and a [summary](#) are available on the Senate website.

Two of the bills/provisions included in the *Opioid Crisis Response Act*, one related to FDA packaging authority and the other related to FDA and Customs and Border Protection coordination, were previously released by HELP Committee Chairman Lamar Alexander (R-Tenn.).

CARA 2.0

In the Senate, a bipartisan group of senators introduced their own follow-up bill (S. 2456) to CARA. This bill provided a basis for the aforementioned House CARA 2.0 legislation, which is identical to its House corollary (H.R. 5311) and is also called CARA 2.0.

The sponsors include Sens. Rob Portman (R-Ohio), Sheldon Whitehouse (D-R.I.), Shelley Moore Capito (R-W.Va.), Amy Klobuchar (D-Minn.), Dan Sullivan (R-Alaska), Maggie Hassan (D-N.H.), Bill Cassidy (R-La.) and Maria Cantwell (D-Wash.). The [section by section](#) may be found on Sen. Portman's website.

Comprehensive Addiction Resources Emergency Act of 2018

Sen. Elizabeth Warren (D-Mass.) has a draft bill titled *The Comprehensive Addiction Resources Emergency Act of 2018*. The Act establishes a pilot program similar in structure to the Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS program, allowing HHS to award grants to eligible entities to create new or expand existing centers to serve as "Comprehensive Opioid Recovery Centers." States with higher overdose death rates, such as West Virginia and New Hampshire, would be given priority for these grants.

Administration Opioid Initiatives

The White House released the President's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand last week. The Trump Administration's three-pronged approach aims to slow overprescribing, reduce the supply of illicit drugs and increase access to evidence-based treatment for those suffering from addiction. Many of the policies contained in the plan stem from the recommendations of the President's Opioid Commission released in November. The Administration's goal is to reduce the number of opioid prescriptions by one-third nationwide during the next three years.

The White House proposal would tighten the number of prescriptions that can be reimbursed in the Medicaid program. It would also create and incentivize states to move to a national PDMP, which would provide greater PDMP coverage given that only 11 states have enacted legislation to establish state-based PDMPs and that many of those are not operational yet. The Administration plan also calls for increasing first responders' supply of naloxone and expanding the use of medication-assisted treatment (MAT). All federal inmates would be tested for opioid addiction and provided options for treatment upon completion of their sentences. The plan also includes new public outreach to deter drug use. The Administration expresses opposition to medically supervised drug consumption, noting the lack of evidence supporting the efficacy of such facilities.

Concerning naloxone, an opioid receptor antagonist used to block the effects of opioids during an overdose, U.S. Surgeon General Jerome Adams issued a rare [public advisory](#) last week encouraging more Americans to carry naloxone with them, including those who take opioids for pain, those misusing opioids, and those in contact with individuals experiencing opioid addiction.

National Institutes of Health (NIH)

The [NIH announced](#) it is nearly doubling its funding, from \$600 million in FY 2016 to \$1.1 billion in FY 2018, for research on opioid misuse and alternative chronic pain treatments as part of a new initiative aimed at accelerating research into evidence-based ways to stem the U.S. opioid epidemic. One of the bills currently being considered by Congress and included in the Senate's *Opioid Crisis Response Act of 2018* is the bipartisan, bicameral *ACE Research Act* (H.R. 5002/S. 2406), which would add greater flexibility to the NIH to promote research on non-addictive pain therapies.

HHS-Medicare Advantage/Part D

The Centers for Medicare & Medicaid Services (CMS) finalized the [Medicare Advantage and Part D Rate Announcement and Call Letter](#) this week. This is the finalized annual update to the Medicare Advantage

and Part D programs, which includes finalized payment updates and policy changes for payment in calendar year 2019.

CMS advanced policy changes to the Part D program to combat the opioid crisis and implement CARA. Specifically, the Final Rule calls on all Part D sponsors to limit initial opioid prescriptions for treatment of acute pain. CMS said it will require Part D plans to implement a "hard" point-of-sale opioid safety edit that limits initial prescriptions to a seven-day supply. CMS declined to set a daily dose maximum, noting that commenters were unable to reach a consensus on such a proposal.

The agency said it also expects Part D plans to set "soft" point-of-sale opioid safety edits that alert the pharmacist if the patient is taking another opioid. These new safety edits and alerts should serve as specific guidelines for clinicians and as a means to prompt much-needed and recurring conversations between prescribers and patients about opioid risks, appropriate pain management expectations, and individual patient needs and preferences.

For so-called "high risk" opioid users, the rule says the existing CMS Overutilization Monitoring System (OMS) will be integrated into drug management programs so prescribers and pharmacies can limit these beneficiaries' access to frequently abused drugs.

CMS said the new opioid policies will not affect beneficiaries who are receiving opioids for cancer-related pain or palliative and end-of-life care, nor those who are in hospice or long-term drug management programs.

Additionally, CMS will create guidance for treating chronic pain and opioid-naïve patients. CDC's 2016 guidelines focus only on opioid prescriptions for chronic pain. CMS' new, more targeted guidelines acknowledge the increased risk of abuse for opioid-naïve patients (6 percent-8 percent of opioid-naïve patients undergoing non-cancer procedures develop new, persistent opioid abuse) as well as the need to establish clear and consistent guidelines for each population.

Substance Abuse and Mental Health Services Administration (SAMHSA)

Title 42 of the Code of Federal Regulations Part 2 (42 CFR Part 2) controls the release of patient information about treatment for substance use disorders. In 2016, SAMHSA released a proposed rule to update the regulations, reduce provider burdens and facilitate information exchange. SAMHSA recently released a final rule and supplemental notice of proposed rulemaking that takes some steps to modernize Part 2, but some members of Congress believe the agency did not utilize its full legal authority to modernize the program. Accordingly, Rep. Markwayne Mullin (R-Okla.) is leading the bipartisan *Overdose Prevention and Patient Safety Act* ([H.R. 3545](#)), which would amend 42 CFR Part 2.

Food and Drug Administration (FDA)

The FDA announced in a budget justification document released in early April that the agency intends to spend \$10 million in FY 2019 related to combating the opioid epidemic, including accelerating the development of generic abuse-deterrent formulations (ADFs) of opioids and expanding access to naloxone by shifting its prescription status to over-the-counter (OTC). The FDA has also recently released analysis suggesting that one day of opioids is sufficient to control pain after many common surgical procedures, furthering cementing the agency's interest in addressing the opioid epidemic.

Department of Justice (DOJ)

As seen in the FY 2018 omnibus provisions, Congress has shown great interest in providing additional resources to DOJ to address the opioid crisis. In late February, DOJ established the Prescription Interdiction and Litigation (PIL) Task Force, which will coordinate with HHS and other federal agencies on law enforcement actions against those that further the opioid epidemic. U.S. Attorney General Jeff Sessions has also expanded the DEA's authority and enforcement teams, and has worked with the DEA to place all fentanyl analogues into Schedule I under the Controlled Substances Act. Finally, DOJ has made multiple announcements about its official interest in pursuing legal action against companies that manufacture opioids.