THE NATIONAL CATHOLIC BIOETHICS CENTER

Upholding the Dignity of the Human Person in Health Care and Biomedical Research since 1972

March 31, 2023

Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: ''Docket No. DEA–407.'' RIN 1117–AB40 Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

Dear Drug Enforcement Administration:

The National Catholic Bioethics Center (Center) would like to provide public comment on the proposed rule, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*.

The Center is a non-profit research and educational institute which for over fifty years has been committed to providing education, guidance, and resources to individuals, institutions, and the larger society, promoting the dignity of the human person in health care and biomedical research. We provide educational programming and consultations to individuals and institutions, including health care institutions and health care providers, seeking its guidance in the domain of bioethics. The Center sponsors educational opportunities to those seeking to be credentialed bioethicists, and collaborates with institutions of higher education in programming, leading to two graduate degrees in the field of bioethics. The Center has been at the forefront of the effort to navigate the difficult waters of bioethical dilemmas in medicine, law, and culture for more than fifty years. Not only have we taught thousands of students and completed tens of thousands of free consultations, we have also assisted health care institutions and providers in addressing the most challenging bioethical questions which society has confronted.

With this strong history of addressing the bioethical challenges of our time, the Center has strong concerns related to the escalation of substance abuse, as well as lethal addictions. Health care delivery cannot abandon those caught in the tragedy of addiction, often through no fault of their own, fostered by indiscriminate prescribing of controlled substances initially for legitimate medical purposes.

Health care must be delivered within a system that promotes a solid health care provider-patient relationship. Such relationships have been threatened, especially by the COVID-19 Pandemic during which a legitimate need existed, and continues to exist, for telemedicine-delivered health care. This situation has been compounded by the negative impact of the COVID-19 Pandemic on mental health. Statistics indicate that there has be a significant increase

NCBCENTER.ORG 600 REED ROAD, SUITE 102, BROOMALL, PA 19008 (215) 877-2660 (215) 877-2688 FAX

in mental health diagnoses,[1] self-medication to alleviate the suffering they create, and alarmingly, drug overdoses.[2] Tragically, suicide ideations have increased significantly.[3] Unfortunately, when states provide for physician assisted suicide (so called "Aid in Dying" or "Death with Dignity" laws) evidence demonstrates that during the COVID-19 Pandemic requests for controlled substances to end one's life also have increased.[4]

Telemedicine is a great asset to meeting the health care needs of the American public. However, the potential for fraud and abuse, especially in the prescribing and use of controlled substances, is great. Patients with legitimate needs for a controlled substance are suffering, and such suffering has many dimensions, including psycho-social factors that lead to substance abuse. More than a prescription is needed; also needed is engagement within an established professional relationship with a trusted health care provider. Such a relationship, with at least an initial in-person medical assessment, is critical to identifying what is needed to provide for the best interest and the total wellbeing of the patient.

Thus, while it is understood that during the COVID-19 Public Health Emergency adapted regulatory provisions have been necessary, they have come at a cost, not only to the provider-patient relationship, but also to the wellbeing of some individuals and the society at-large, as demonstrated by the aforementioned statistics. The Center welcomes regulatory provisions that could attenuate some of these challenges, while at the same time not impacting negatively

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[1] "In a 2021 study, nearly half of Americans surveyed reported recent symptoms of an anxiety or depressive disorder, and 10% of respondents felt their mental health needs were not being met. Rates of anxiety, depression, and substance use disorder have increased since the beginning of the pandemic. And people who have mental illnesses or disorders and then get COVID-19 are more likely to die than those who don't have mental illnesses or disorders." See, National Institutes of Health, "Mental Health During the COVID-19 Pandemic," National Institutes of Health COVID-19 Research (Updated March 20, 2023). Available at https://covid19.nih.gov/covid-19-topics/mental-health#:~:text=If%20you%20get%20COVID%2D19,Psychosis.

[2] "There were 91,799 drug overdose deaths in the U.S. in 2020, a 30% increase from 2019, which began accelerating in March 2020." See, Lauren J. Tanz, ScD; Amanda T. Dinwiddie, MPH; Stephanie Snodgrass, MPH; Julie O'Donnell, PhD; Christine L. Mattson, PhD; Nicole L. Davis, PhD, "A qualitative assessment of circumstances surrounding drug overdose deaths during early stages of the COVID-19 pandemic," *SUDORS Data Brief*, Number 2, Centers for Disease Control and Prevention (August 2022). Available at https://www.cdc.gov/drugoverdose/databriefs/sudors-2.html#:~:text=during%20future%20emergencies.-,Introduction,began%20accelerating%20in%20March%202020.&text=The%20COVID%2D19%20pandemic%20was,stay%2Dat%2Dhome%20orders.

[3] 10.7 percent of respondents studied reported suicide ideations in the past 30 days during COVID-19 pandemic as reported on "Table 1: Respondent characteristics and prevalence of adverse mental health outcomes, increased substance use to cope with stress or emotions related to COVID-19 pandemic, and suicidal ideation — United States, June 24–30, 2020." See, Mark É. Czeisler, *et at.,* "Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States," *Morbidity and Mortality Weekly Report* (Centers for Disease Control and Prevention, June 24–30, 2020). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7440121/.

[4] "During 2022, 431 people [in Oregon] received prescriptions for lethal doses of medications under the provisions of the Oregon DWDA, compared to 384 reported during 2021." See, Oregon Health Authority, Public Health Division, *Oregon Death with Dignity Act* (2022 Data Summary, p. 6). Available at https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/DEATHWITHDIGNITYACT/Documents/year25.pdf.

those experiencing chronic pain and well-served by palliative care. For these and other patients telemedicine has the potential to promote and enhance the physician-patient relationship, especially when societal and demographic forces challenge that relationship.

The Center supports public policy that protects patients from indiscriminate prescribing of controlled substances, particularly narcotics, leading to the aforementioned escalation of drug addiction, overdoses, and even death. We support provisions that require physicians to truly engage with their patients before prescribing controlled substances, so that the best interest of the patient always is addressed. This would prevent what virtually could be described as negligence, and even patient abandonment at the very point in which the physician-patient relationship needs to be strengthened. Such abandonment is actualized by physician assisted suicide which could be facilitated by telemedicine that provides for the prescribing of these substances without an in-person encounter.

Thus, National Catholic Bioethics Center recommends:

1. All Schedule II and all narcotic Schedule III-IV controlled substances only be telemedicine-prescribed after a documented initial (occurring within the last 30 days) in-person medical assessment by a licensed prescriber has occurred.

2. For all non-narcotic Schedule III-IV drugs a 30-day supply can be prescribed via telemedicine before the required in-person medical assessment occurs, **IF** the prescription is not being written pursuant to a state's "Aid in Dying' or "Death with Dignity" law.

The latter provision needs to be addressed specifically in the final rule since most of the controlled substances used in physician assisted suicide cocktails are non-narcotic. Only one of the drugs used in physician assisted suicide is a narcotic .[5] Since state laws providing for physician assisted suicide ("Aid in Dying" or "Death with Dignity"), represent a regulated activity, the federal government needs to collaborate with state governments to assure there is no utilization of the law through telemedicine. No patient should be prescribed a lethal dose of a medication, but to do so without an in-person medical evaluation is the ultimate abandonment of a patient by the health care professions, and by government agencies that allow this to occur.

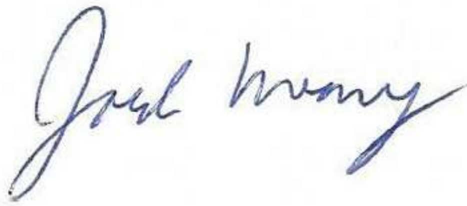
Again, we support the use of telemedicine which promotes and enhances the provider-patient relationship, especially when societal and demographic forces challenge that relationship. But every regulatory effort must be made to prevent the existing crises that have occurred through

[5] Commonly used drugs in physician assisted suicide, and their FDA Schedule: Midazolam or Diazepam (an anxiolytic), a Schedule IV non-narcotic controlled substance; Propofol (an anesthetic coma-inducing agent), a Schedule IV non-narcotic controlled substance; Rocuronium, or Cisatracurium, (neuromuscular blockers to stop respiration), not scheduled controlled substances; Morphine (narcotic), a Schedule II narcotic; Barbiturates (depressant), a Schedule IV non-narcotic controlled substance; Digoxin (anti-arrhythmic), not a Scheduled controlled drug; Amitriptyline (antidepressant), not a Scheduled controlled drug; and Propranolol (Cardiac), not a Scheduled controlled drug.

the prescribing of controlled substances when barriers to the provider-patient relationship are not addressed. The ultimate fostering of the best interest of the patient is through an in-person relationship with the health care provider.

Thank you for the opportunity to address the concerns of the National Catholic Bioethics Center.

Sincerely yours,



Joseph Meaney, PhD
President