C+TAC
COALITION TO TRANSFORM ADVANCED CARE

March 18, 2025

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

Re: Special Registrations for Telemedicine and Limited State Telemedicine Registrations

Submitted electronically via www.regulations.gov

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule regarding its effect on those living with serious illness.

C-TAC is a national, non-partisan, not-for-profit coalition dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high-quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC comprises more than 200 national and regional organizations, including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

Our comments on aspects of the proposed rule support the need for safety in this area but outline our concerns that, in the interest of that safety, some of the proposed changes will reduce access to care and add elaborate and expensive new administration burdens to health care providers, particularly to those caring for people living with serious illness unable to participate in telehealth visits. Specifically:

Special Registration Requirement
While we appreciate the concerns around prescribing opioids or schedule II-V drugs via telehealth, we note that a special registration was not required during the COVID-19 public health emergency and are unaware of any evidence that the lack of such a registration was problematic at the time. Instead, it seems now to be adding an expensive and burdensome hurdle that will reduce access to use of these FDA-approved medications for those with serious illness who very much need them. The unfortunate result of this Special Registration will be to limit the number of practitioners in palliative care and hospice who can prescribe these drugs via telehealth, causing patients in need of them to have to try to find a practitioner who can. It will also limit programs relying on telehealth to provide prompt treatment, especially in rural areas, from being able to do so. We therefore recommend that it not be included in the final rule.

Our specific concerns are:

- Palliative care and hospice practitioners- While we appreciate the inclusion of hospice and palliative care practitioners in this program, we have concerns with the requirement that in order to order a controlled substance, the provider must have a telehealth encounter with the patient. While this makes sense for non-emergent use of these medications, there are situations where a home-based palliative care or hospice practitioner is asked to order these medications for a patient they have not seen before. As a previous hospice nurse practitioner, I was on call and ordered such medications based on the hospice registered nurse's in-person assessment of the patient. Having to schedule a telehealth visit in such a situation would be impractical, and impossible with a dying patient. Therefore, unless there is some other change possible, hospice and palliative care practitioners should be exempted from this proposed Special Registration.

- Board certification- We appreciate the thinking behind requiring board certification for non-physician practitioners (NPPs) to qualify for a Special Registration but this will again be problematic for hospice and palliative advanced practice nurses. As of February 26, 2025, there are only 2,638 such nurses holding the Advanced Certified Hospice and Palliative Nurse (ACHPN®) certification yet many more who practice in those fields, not all of whom are board certified in the other required specialties of psychiatric or psychological disorders, pediatric care, or neurological disorders. Additionally, states like Maryland do not recognize the ACHPN certification for licensure as it falls outside the population foci approach defined by the Maryland Board of Nursing. Nurse practitioners there must be board certified in one of the approved specialties to practice in the state, which do not include some of the proposed required certifications. This discourages some from seeking additional hospice or palliative care certification as it is administratively and financially costly to maintain dual certifications. We therefore recommend that board certification not be a requirement for NPPs to prescribe these medications via telehealth. If they are legally entitled to do so in their states that should be confirmation enough.

- Cost/Administrative burden- The Special Registration would be in addition to the Special Registrant's already expensive standard DEA registration (an additional $888) and would need to be renewed every three years. This dual registration could be unaffordable for either practitioners who must pay for these registrations on their own or for small health care organizations who pay for them on behalf of their practitioners. The consequence of that would also be to reduce the number of practitioners able to treat patients needing these medications by telehealth, another barrier to access to care. We therefore recommend that the cost of this Special Registration be significantly reduced.

- Audio-Video Telecommunication Systems- Again, while we appreciate the concern for safety and possible drug diversion, requiring video telecommunication is problematic for those patients who lack access to smart phones, other such devices, broadband, or cell phone service. The pandemic taught us, and CMS subsequently confirmed, that allowing audio-only telehealth was appropriate for patients who preferred talking by phone or land line or had no other options. While patients can decline audio-visual telehealth in this proposed rule, its inclusion may cause providers to pressure patients nonetheless. Please revise this rule to allow both audio-visual and audio-only telehealth in line with CMS policy.

- Terminology- We have two concerns here:
    - *Ambiguous language regarding the ability of providers to obtain these registrations*-Practitioners will need to show that they have a "legitimate need" for the Special Registration and that "such need warrants the authorization of prescribing of Schedule II controlled substances in addition to Schedules III through V controlled substances." Further, "such authorization is reserved only for the most compelling use cases, ensuring that Schedule II prescribing via telemedicine is used only when necessary." This language is probably intentionally vague but in not being objective it could exclude some practitioners who have appropriate need for such registration and further limit access to care. Please clarify what "legitimate need" is in the final rule.

    - *Use of "mid-level" to describe non-physician practitioners*- The term ""mid-level" is derogatory as it suggests these non-physician practitioners (NPPs), the term that CMS generally uses instead, are lesser than physicians when they are in fact independent practitioners and, in the states where they have prescriptive authority, can independently prescribe these medications. As a nurse practitioners with a doctorate in nursing practice, I refer you to the American Association of Nurse Practitioners statement on this label and urge you to use CMS's NPP term instead.

Prescription Limits on Telemedicine

The proposal that a practitioner's Schedule II prescriptions via telemedicine cannot exceed 50% of their total Schedule II prescriptions per month will also be problematic for those hospice or palliative care practitioners in programs doing much of their care via telehealth. Some of these serve rural areas where it is not feasible for patients to come in for these interactions. This recent journal article outlines such a situation and the benefits of telehealth for such patients. Therefore, please allow more than 50% for such providers.

Patient Verification Photographic Record

Again, while we appreciate the value of being able to confirm a patient's identity via visual communications, this requires not only that such visual communication be available but that the person have the technological dexterity to share their record that way. As noted previously,

this would not be possible for many hospice patients and particularly for those who are actively dying. Please loosen this requirement in the final rule.

Same-State Registration Rule
Again, we appreciate the concern for safety and the reality that different states have different rules about prescribing controlled substances but requiring that practitioners be physically located in the same state as the patient when prescribing Schedule II medications limits cross-state prescribing in border states and will be another barrier to access to care. As noted above, making practitioners get a State Telemedicine Registration for every state in which they intend to prescribe controlled substances via telemedicine adds cost and complexity to an already expensive new registration. Please revise the final rule to allow more flexibility in this respect.

Mandatory Prescription Drug Monitoring Program (PDMP) Checks
We appreciate the value of checking a PDMP to ensure the practitioner is aware of the patient's past history with controlled substance prescriptions. However, while this is generally feasible to do within the same state, it is not possible across other and certainly not all fifty states and territories. Many hospices lack robust electronic health systems that do not interface with PDMPs and checking ones by hand would be very labor intensive. This could further delay care, especially in rural areas. Therefore, please reduce this requirement in the final rule.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Dr. Marian Grant, Senior Regulatory Advisor, C-TAC, at mgrant@thectac.org.

Sincerely,

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