March 31, 2023

Scott Brinks, Federal Register Liaison Officer
Drug Enforcement Administration (DEA)
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152


Submitted electronically via regulations.gov

Dear Mr. Brinks,

UnityPoint Health appreciates this opportunity to provide comments on this proposed rule related to the telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation. UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health appreciates the time and effort of DEA in developing this proposed rule. As a member of the American Hospital Association (AHA), UnityPoint Health wholeheartedly supports their comment letter dated March 29, 2023. Due to the importance of this issue and impact on our patients, providers, and communities, UnityPoint Health has provided some specific operational concerns to illustrate unintended consequences of this proposed rule should it be adopted and promulgated without revision.

GENERAL COMMENTS

DEA invites comments concerning whether any clarifications or other regulatory provisions are warranted to ensure appropriate access to care, consistent with effective controls against diversion and otherwise consistent with the public health and safety. Comments are requested on whether the rule should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications; proposed practitioner recordkeeping obligations; whether the proposed 30-day maximum supply, or other maximum day supply, should be imposed for controlled substances being prescribed via telemedicine prior to an in-person evaluation; and any additional safeguards or flexibilities that should be considered with respect to this rule.
Comment: UnityPoint Health is extremely concerned that the proposed rule will lead to undue barriers to mental health and substance use disorder treatment for all ages, including children on schedule II medications. The proposed tele-prescribing restrictions conflict with Biden-Harris Administration strategy to address the national mental health crisis. These restrictions do not “strengthen system capacity” which is a core objective of this strategy, but these restrictions do further fragment the system and aggravate the workforce shortage. Below we have outlined some service delivery and operational implications that will likely result and prevent timely access to vital treatment by countless individuals with mental health and substance use disorders. These implications underpin the AHA recommendations, and UnityPoint Health also strongly encourages DEA to (1) create a special registration process regulation to identify a pathway to waive in-person evaluations prior to the prescribing of controlled substances for practitioners who register with the DEA, and (2) extend the waivers for the in-person visit requirement for prescribing of controlled substances until it can, with significant stakeholder input, develop and propose a framework for a special registration process for prescribing controlled substances via telemedicine.

Disproportionate impact on children: Many children rely on schedule II medication to engage in a conventional classroom. These children rely on telehealth providers to access these medically necessary medications particularly in rural states. It is common for these telehealth services to be delivered in schools and small satellite clinics where other DEA registered practitioners are not physically present. Telehealth enables UnityPoint Health to provide convenient service locations, reduce missed appointments, and efficiently utilize our practitioners. UnityPoint Health operates telehealth services in both schools and satellite locations. When telehealth is provided in the school setting, this proposed rule would place an undue burden on families and children requiring a child to be removed from school to travel to a clinic for treatment. This not only adds time and travel expense, but causes additional educational disruption with more missed classroom time. In some rural environments, service delivery is offered through centrally located satellite clinics whereby a nurse is present at a community outreach location and a provider attends via telehealth. These regional satellite clinics would close under this proposed rule, and many rural children and adults with socio-economic needs will be forced to travel 60+ miles to receive services at our traditional clinics where other DEA registered practitioners provide in-person services.

Exacerbation of the mental health professional shortage: The proposed rule prohibits providers from prescribing more than a 30-day supply of medications without an in-person medical evaluation. It is no secret that the United States has a significant psychiatric workforce shortage. According to the Association of American Medical Colleges, “the United States does not have nearly enough mental health professionals to treat everyone who is suffering. Already, more than 150 million people live in federally designated mental health professional shortage areas. Within a few years, the country will be short

1 https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/

2 Id. Page 2, “At the center of our behavioral health crisis is a severe workforce shortage. We do not have enough providers, and they are not located in the right places or providing the right services to meet Americans’ needs. Even where there are sufficient providers, the fragmentation and inconsistency of the current system can make it difficult for people to find the right level of care.”
between 14,280 and 31,109 psychiatrists, and psychologists, social workers, and others will be overextended as well."³ For UnityPoint Health’s three-state service area, the need is significant (see table below).

<table>
<thead>
<tr>
<th>State</th>
<th>Licensed Psychiatrists⁴</th>
<th>Provider per capita ratio⁵</th>
<th>Practitioner Shortage⁶*</th>
<th>Percent of Need Met⁷</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illinois</td>
<td>2147</td>
<td>1:5860</td>
<td>425</td>
<td>22%</td>
</tr>
<tr>
<td>Iowa</td>
<td>402</td>
<td>1:7961</td>
<td>72</td>
<td>38.2%</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>845</td>
<td>1:845</td>
<td>131</td>
<td>38.5%</td>
</tr>
</tbody>
</table>

*Practitioner Shortage is the number of practitioners need to remove HPSA designation.

It should also be noted that psychiatrists are disproportionately located in urban areas, so even the alarming statistics minimize the access to psychiatrists in rural areas particularly if the proposed telehealth limitations are enacted. In the context of workforce constraints, requiring prescribers to see patients, in-person, every 30 days in order to maintain their prescriptions is unrealistic and supplants medical standards of care. This proposed universal appointment/in-person visit frequency is not medically indicated or necessary, would create an unprecedented demand for in-person appointments that would cripple the industry, and ultimately would result in inaccessible treatment – quite simply, new patient openings for psychiatrists would be non-existent, even for those in crisis; hospitals and emergency rooms would be increasingly overrun with patients unable to find treatment options; and increasing pressure on psychiatrist caseloads may result in further physician burnout and further degrade issues with psychiatrist recruitment and retention. For patients who rely on medication for substance use disorders, this 30-day limitation is especially concerning and seems contrary with SAMHSA’s intent to make Medication Assisted Treatment more accessible to combat the Opioid Pandemic. In lockstep with the AHA, UnityPoint Health recommends removing the 30-day supply limit and instead allowing clinicians to determine the frequency of in-person exams.

Affront to tele-hospitalist and tele-nocturnist models: The proposed rule will adversely impact communities that UnityPoint Health currently serves through a tele-hospitalist or tele-nocturnist model, especially hospitals located in rural and underserved areas. These telehealth models provide

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⁴Kaiser Family Foundation, State Health Facts, Professional Active Specialist Physicians by Field, January 2023, accessed at https://www.kff.org/other/state-indicator/physicians-by-specialty-area/?dataView=0&currentTimeframe=0&selectedDistributions=psychiatry&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
⁶Kaiser Family Foundation, State Health Facts, Mental Health Care Health Professional Shortage Areas (HPSAs), September 30, 2022, accessed at https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
⁷Id.
real-time diagnoses and treatment from licensed, but remote, physicians who provide the equivalent quality patient care as an in-house provider. Tele-hospitalist and tele-nocturnist allow patients to be safely cared for at their local hospital – transfers are reduced, and higher acuity patients are able to remain in their home communities. The proposed DEA in-person medical evaluation requirement directly challenges these virtual models and poses the greatest threat to access for our small rural communities where UnityPoint Health is now only able to sustainably deliver 24/7 care through a technology modality. For our tele-hospitalists, the proposed rule limits their scope of practice because their licenses support the prescribing of controlled substances. As written, this rule disrupts provider workflow and duplicates work effort. Despite medical evaluation by a tele-hospitalist, the tele-hospitalist would not be able to discharge a patient independently who needs a prescription for a controlled substance. Instead, the discharge would be pending the completion of the proposed face-to-face stipulation by an in-house provider. Only after the completion of the in-person visit would a tele-hospitalist be able to finish the discharge process. We anticipate that discharge delay will correspond to a decrease in patient satisfaction and an unnecessary increase in the patient’s length of stay. Similar to our tele-hospitalists, our tele-nocturnists would not be able to prescribe appropriate medications for the patient’s condition. In practice, this proposed rule does not promote efficient and timely care; rather, we predict it will result in duplicative work effort, longer lengths of stay, delays in patient care, unnecessary transfers leading to emergency room boarding, and ultimately restrictions or closures of care sites due to no in-person coverage disproportionately impacting rural and underserved areas.

Misaligned with originating site distinctions: Building upon the arguments of a tele-hospitalist, the proposed rule does not generally account for differences in originating site locations. For example, it appears this proposed rule targets providers prescribing controlled substances via telehealth when such services are delivered in the patients’ home. Although many telehealth services are delivered with an originating site of the patients’ home, this rule does not appear to contemplate telehealth services where a healthcare facility is the originating site, such as a clinic or hospital. Having a healthcare facility as the originating site is extremely common, and this type of practice carries with it the same safeguards as a patient who is seeing a provider face-to-face. The CMS CY2023 Physician Fee Schedule final rule acknowledged this and did not include a face-to-face encounter requirement in order to bill mental health telehealth services for patients seen in a healthcare facility based on the place of service listed on the claim.

Incompatible with state regulations: UnityPoint Health is extremely grateful that Congress has recognized the importance of telehealth during the public health emergency (PHE) and extended the majority of telehealth flexibilities through December 31, 2024.8 Many states have also recognized telehealth as an important method to deliver health care services resulting in a variety of state telehealth laws and regulations. For example in Iowa, a licensee who “uses telemedicine shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters.”9 The proposed DEA rule appears to contradict this state law leaving practitioners in a quagmire. We respectfully request that DEA perform a cursory review of state laws to determine the true impact of this proposed rule on

8 https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.xml
patients and providers and take this into consideration when proposing new restrictions.

We are pleased to provide input on this proposed rule and its impact on our health system, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Maggie Frost, RN-BSN  
Operations Director, Inpatient Medicine Service Line

Aaron Mchone, MBA  
Behavioral Health Service Line Operations Director

Cathy Simmons, JD, MPP  
Executive Director, Government & External Affairs