799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

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Submitted electronically via www.regulations.gov

Administrator Anne Milgram
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield VA 22152

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407)

Dear Administrator Milgram,

Vizient, Inc. appreciates the opportunity to respond to the Drug Enforcement Administration (DEA) Proposed Rule on telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation (hereinafter "Proposed Rule"). The Proposed Rule would, in effect, continue to support certain patient's access to care, as provided during the COVID-19 Public Health Emergency (PHE). While Vizient applauds DEA for issuing the Proposed Rule as the end of COVID-19 PHE rapidly approaches, we urge that several policies be modified to better support patients and providers, and that a final rule be issued promptly as providers will need time to interpret the final rule and adjust their practices to support implementation.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates the efforts of DEA to issue the Proposed Rule before the end of the COVID-19 PHE as several flexibilities that have been afforded to providers and patients to support access to care will expire. While Vizient recognizes the challenges and devastation of the opioid epidemic, we similarly are sensitive the harm that could occur if patients' medications or care regimen is disrupted. In separate comments, Vizient responds to DEA's proposed rule regarding telemedicine prescribing of buprenorphine for treating opioid use disorder. Generally, for both proposals, Vizient urges DEA to modify proposed policies to better ensure a smooth transition from the flexibilities that have been provided during the PHE and to broaden policies to better support patient care needs.

COVID-19 PHE Transition Period

DEA proposes a policy that would facilitate a 180-day transition of doctor-patient relationships from the use of telehealth prescribing flexibilities established during the COVID-19 PHE to the prescribing

authority terms set forth in the Proposed Rule.[1] More specifically, the scope of medications that may be prescribed if the prescribing practitioner has a telemedicine relationship that was established during the COVID-19 PHE[2] may include Schedule II medications and narcotic controlled substances. In addition, the 30-day supply limitation would not apply to prescriptions issued by a practitioner who has a telemedicine relationship established during the COVID-19 PHE. Vizient understands these prescribing flexibilities would last for 180 days after the COVID-19 PHE, if such a telemedicine relationship was established during the pandemic. Vizient appreciates DEA's efforts to prevent disruptions to care and offers additional information and suggestions for consideration.

During the PHE, as shown in Image 1, telehealth utilization has remained high despite the reversion to in-person visits in 2021. Further, Vizient anticipates that 27% of evaluation and management visits will occur virtually by 2032.[3] Therefore, Vizient believes it is critical that policy be carefully crafted to prevent disruption to care given the important and growing role of telehealth. Vizient is concerned that the proposed 180-day transition of doctor-patient relationships would be one way in which care could be disrupted, especially for patients in rural communities or those who are challenged in accessing a provider. Therefore, Vizient encourages DEA to consider potential exemptions to this 180-day transition period so that patient care is not disrupted, and public health is still prioritized.

Further, Vizient notes our concern of potential unintended consequences of the proposed policy should patients abruptly lose access to controlled substance prescriptions. In the Proposed Rule, it is unclear why DEA selected a 180-day transition period, or what research and data was considered in crafting a policy that could impact patient safety. Vizient suggests DEA work closely with providers and patients to identify alternative transition plans that better account for different circumstances in which a patient is unable to meet with their prescriber in-person. While Vizient recognizes that the end of the COVID-19 PHE is near, making it more challenging for such collaboration to occur, we suggest that DEA finalize a longer transition period and provide plans to allow for additional, future rulemaking.

[1] In the Proposed Rule, DEA provides limitations (e.g., up to 30-day initial prescription and in-person visit requirement for additional prescriptions) for Schedule III-V non-narcotic controlled medications and buprenorphine and a ban on schedule II and narcotic controlled medications prescribed solely via telehealth.

[2] As provided in the Proposed Rule, "An individual practitioner and a patient have a telemedicine relationship established during the COVID–19 public health emergency if: (1) The practitioner has not conducted an in-person medical evaluation of the patient; (2) The practitioner has prescribed one or more controlled substances based on telemedicine encounters during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 and pursuant to the designation pursuant to that public health emergency on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under section 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States; and (3) No more than 180 days have elapsed since [EFFECTIVE DATE OF RULE] or the end of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019, whichever is later."

[3] https://www.sg2.com/wp-content/uploads/2022/11/2022_IoC_Forecast_Media.pdf

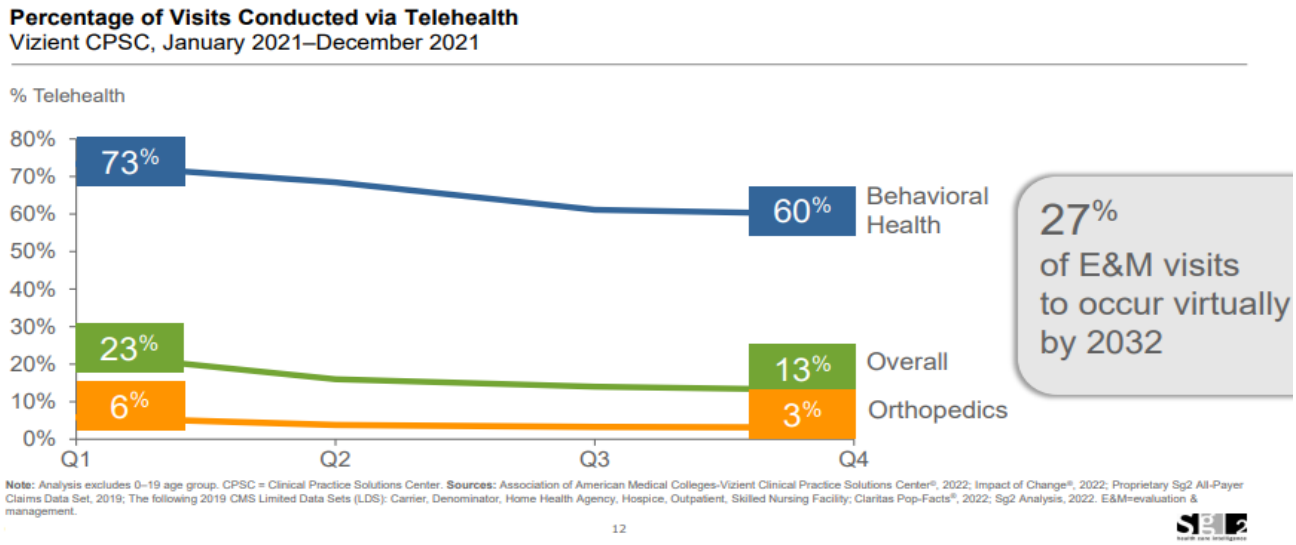

Image 1. Graph of visits developed by Sg2, a Vizient company, conducted via telehealth from January 2021 – December 2021 and projection of future virtual care utilization.[4]

Qualifying Telemedicine Referral

In the Proposed Rule, DEA proposes to define "qualifying telemedicine referral"[5] and that this referral would permit the prescribing of all types of controlled substances, consistent with applicable state and federal laws. Vizient appreciates DEA's efforts to create additional flexibilities regarding in-person medical evaluations. However, Vizient is concerned that patients, such as those in rural communities who are particularly challenged to see a single practitioner in-person, may still be challenged to meet this requirement. Also, local practitioners may not have technical capabilities or may be otherwise reluctant to connect with and collaborate with other providers as envisioned in the Proposed Rule. Further, the proposed policy could place additional financial strain on patients who are unable to afford visits with multiple providers for a single prescription. Vizient encourages DEA to work with a range of providers to consider easing the requirements and allowing for different circumstances to meet the definition of qualifying telemedicine referral. We also recommend DEA rely on feedback from practitioners that would be providing qualifying telemedicine referrals to better understand potential hesitations or drawbacks of the proposed policy.

Also, Vizient appreciates the different examples DEA provides in the Proposed Rule to clarify prescribing when there is a qualifying telemedicine referral. However, the examples do not address circumstances where the patient has already identified a prescriber, or the patient already has a relationship with such a prescriber. Vizient suggests DEA provide additional examples to clarify this process.

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[4] Association of American Medical Colleges-Vizient Clinical Practice Solutions Center©, 2022; Impact of Change®, 2022; Proprietary Sg2 All-Payer Claims Data Set, 2019; The following 2019 CMS Limited Data Sets (LDS): Carrier, Denominator, Home Health Agency, Hospice, Outpatient, Skilled Nursing Facility; Claritas Pop-Facts®, 2022; Sg2 Analysis, 2022. E&M=evaluation & management.

[5] As provided in the Proposed Rule "A qualifying telemedicine referral means a referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral must note the name and National Provider Identifier of the practitioner to whom the patient is being referred."

Scope of Prescriptions Permitted via Telehealth without an In-person Medical Evaluation or Qualified Telemedicine Referral
As provided in the Proposed Rule, the agency is not permitting any Schedule II substance or narcotic substance to be prescribed as a result of telemedicine encounters because it would pose too great a risk to the public health and safety given the ongoing opioid epidemic. While Vizient understands the ongoing challenges and devastation associated with the opioid epidemic, we are concerned that the proposed prescribing limitations will impede or disrupt treatment for patients who are uniquely challenged in meeting with a provider, including geographic challenges or financial challenges in having additional visits with a provider, especially if such visits require a co-pay or are otherwise not covered. In addition, the scope of prescriptions that cannot be prescribed via telehealth, as proposed, is broader than opioids as it includes other types of Schedule II drugs such as stimulants.[6] Also, as DEA is likely aware, a range of other policies are being implemented and resources provided to help prevent the ongoing harm caused by the opioid epidemic, including electronic prescribing requirements for certain controlled substances and increasing research and guidance regarding evidence-based treatment. Vizient encourages DEA to consider whether additional safeguards or exceptions could be provided to allow a broader scope of telemedicine prescriptions.

In addition, should the agency finalize the proposed policies, we suggest DEA work with other agencies, provider groups and patients to provide clear guidance, promptly respond to frequently asked questions as issues emerge and consider additional enforcement flexibility. Vizient is concerned the Proposed Rule contains numerous changes, including several new requirements, that would need to be implemented extremely quickly given the COVID-19 PHE ends on May 11, 2023. As such, there could be reluctance to prescribe or dispense schedule II or narcotic prescriptions as compliance systems and processes will need to be established.

Duration of the Initial Prescription
In the Proposed Rule, DEA provides that when only a telehealth visit occurs between a prescribing practitioner and patient, then the initial telemedicine prescription of non-narcotic schedule III-V controlled substances would be for an amount that does not exceed 30 days. Vizient appreciates that the DEA has provided some time for a patient to meet with their provider in-person should a longer prescription be needed. Vizient encourages DEA to consider providers' recommendations and best practices regarding prescribing decisions, including where longer-term prescriptions may be appropriate.

Issuance of Prescriptions for Controlled Medications to the FDA-approved labeling
In the Proposed Rule, DEA seeks comment 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. Vizient discourages DEA from limiting the scope of prescriptions to only the indications contained in the FDA-approved labeling as such a policy would interfere with the practice of medicine. Further, Vizient notes that since pharmacists dispensing medications often do not have access to patients' diagnoses when a prescription is dispensed, such a shift in policy does not reflect current care practices or information sharing.

New Requirements for Practitioners
In the Proposed Rule, DEA outlines various practitioner requirements, including recordkeeping for the prescribing practitioner and practitioner who is physically present for the medical evaluation and

[6] https://www.deadiversion.usdoj.gov/schedules/

mandated reviews of prescription drug monitoring programs (PDMP) in the state where the patient is located. Vizient is concerned that these additional requirements may be excessively burdensome and challenging to implement. For example, the practitioner who is physically present for the medical evaluation may not always know when a controlled substance was prescribed by the prescribing practitioner, yet they would also need to maintain records in these circumstances. The examples provided in the Proposed Rule, while helpful, do not detail how new requirements for practitioners would potentially fit into the care process. Vizient suggests DEA provide more robust examples of all the different provider requirements and to work with providers to confirm the feasibility of such requirements. Should requirements be considered by providers to be excessively burdensome or challenging, we encourage DEA to ease such requirements so that patient care will not be disrupted, while still maintaining public health and safety.

Prescription Notations

DEA proposes to require that telemedicine prescriptions include on the face of the prescription or within the prescription order if prescribed electronically, that the prescription was issued via a telemedicine encounter. DEA notes this proposal would enable DEA investigators to more easily detect abuse patterns in the use of telemedicine. While Vizient appreciate the critical role DEA investigators play in enforcing the nation's drug laws and enhancing public health safety and national security, Vizient is concerned that such a policy may have the unintended consequence of creating unnecessary suspicion and stigma being associated with telemedicine prescriptions, which would negatively impact patient care.

Medication Shortages

In the Proposed Rule, DEA does not address how efforts to support ongoing supply and patient access to medications will be assured, including by potential revisions to Aggregate Production Quotas (APQs) for Schedule II Controlled Substances. During the COVID-19 PHE, a range of supply chain challenges and changes to care delivery occurred, including shifts to telemedicine. These changes are shaping the future of care delivery and can impact other policies, including those related to medications. While the Proposed Rule does not address APQs and seeks to exclude Schedule II substances from telemedicine visit prescribing, Vizient encourages DEA to consider how best to meet patient demand for medications which saw increases in prescriptions during the PHE and are currently in shortage. We also encourage DEA to clarify how it will consider telemedicine prescriptions when setting APQs, including how APQs could potentially be impacted should the 180-day period for COVID-19 prescriptions be finalized and other changes provided in the Proposed Rule.

Special Registration

As provided in law, there are seven potential categories of telemedicine pursuant to which a practitioner may prescribe a controlled medication despite never having evaluated the patient in person. One of these statutory categories is treatment by a practitioner who has obtained a special registration.[7] In the Proposed Rule, DEA indicates that it considered several regulatory alternatives, including only the issuance of "special registration" regulations to allow for the prescribing of controlled substances via telemedicine in different potential circumstances. While Vizient agrees that the regulatory alternatives the agency considered are not preferable due to administrative burden, in addition to timing given the end of the COVID-19 PHE is May 11, 2023, we do request that the agency clarify whether future rulemaking may be forthcoming regarding such a special registration process for the prescribing of controlled substances, including Schedule II and narcotics, without an in-person visit. Vizient strongly

[7] *See* 21 U.S.C. 802(54)(E)

agrees with the need to exercise caution regarding controlled substance prescriptions, including Schedule II medications and narcotics. However, given that patient access to a prescriber for an in-person evaluation will continue to be a challenge if the Proposed Rule is finalized, particularly for patients in rural communities, we encourage the DEA to consider opportunities to better support patient access to care in these types of circumstances.

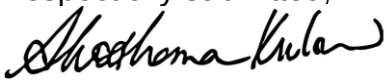
Education and Resources
As the end of COVID-19 PHE approaches, patients and providers will need additional education and resources to minimize disruption regarding changing regulations, including the Proposed Rule, if finalized. Given these anticipated changes, Vizient believes education and resources should be provided to promptly address questions before and after the end of the PHE. Such education and resources should be directed towards both providers and patients. Vizient also encourages DEA to work with other agencies, such as the Centers for Medicare and Medicaid Services, to provide joint education and resources regarding telemedicine prescriptions and prescribing requirements.

Conclusion

Vizient thanks DEA for the opportunity to share feedback in response to the Proposed Rule. We believe it is imperative that the Proposed Rule be promptly finalized, with suggested modifications, to prevent significant disruptions to care. In addition, Vizient emphasizes the importance of ensuring providers and patients have adequate time to adapt to any final policies and that patient care not be needlessly disrupted. As noted throughout Vizient's comments, we appreciate DEA's work to protect public health and safety but do encourage the agency to consider broadening elements of the Proposed Rule.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank the DEA for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me or Jenna Stern at Jenna.Stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,



Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.