

June 19, 2020

Drug Enforcement Administration

U.S. Department of Justice

Submitted electronically at: <https://www.regulations.gov/comment?D=CMS-2019-0090-0001>

Attention: Public Comment for the interim final rule regarding electronic prescribing of controlled substances, published March 31, 2010, at 75 FR 16236

Drug Enforcement Administration:

Thank you for the opportunity to provide input on the interim final rule regarding electronic prescribing of controlled substances (EPCS). The Minnesota e-Health Initiative (Initiative) is pleased to submit comments as a public-private collaborative focused on advancing the adoption and use of electronic health records and other health information technology, including health information exchange. A legislatively authorized 25-member Advisory Committee guides the Initiative (see Appendix A). The Minnesota Department of Health, Center for Health Information Policy and Transformation, coordinates activities of the Initiative.

The Advisory Committee recognizes the need to securely prescribe and dispense controlled substances. Following recommendations from this Committee, Minnesota enacted the first electronic prescription mandate in the country, effective in 2011. While e-prescribing rates are very high, we lag in EPCS with 53.3% of prescribers enabled and 60.5% of controlled substances prescribed electronically by end 2019 (Surescripts National Progress Report). We know that prescribers are continuing to work toward enablement and implementation of EPCS, but we also know that prescribers often fall back on paper scripts (usually ordering through the EHR but then printing the script). This suggests that barriers to EPCS reach beyond the technical implementation, and that guidance is needed to educate prescribers on the need for EPCS, and technical solutions need to fit into their workflow.

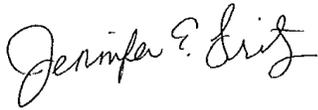
We are also concerned that implementation of EPCS disproportionately challenges small and specialty health organizations. These providers include our federally qualified health centers, rural health providers, and providers who serve patients with complex medical conditions. We encourage the DEA to work closely with technology vendors and standards development organizations to ensure that solutions are nimble to adapt to changes, align with credentialing processes, and integrate efficiently into the prescriber workflow. Further, we want to be sure that these rules don't create unintended consequences, such as prescribers opting to forego their DEA license due to the implementation requirements and thereby not providing needed care for their patients.

Please consider these comments and recommendations related to the EPCS interim rule. They are developed from input from across Minnesota and work of the Initiative. Contact Karen Soderberg,

MINNESOTA E-HEALTH INITIATIVE RESPONSE TO EPCS INTERIM RULE

Supervisor, e-Health and Health Information Exchange, Office of Health Information Technology,  
Minnesota Department of Health at [karen.soderberg@state.mn.us](mailto:karen.soderberg@state.mn.us) with any questions.

Sincerely,



Jennifer Fritz  
Director Center for Health Information Policy and Transformation  
Minnesota Department of Health



Peter Schuna  
Advisory Committee Co-Chair  
Minnesota e-Health Advisory Committee  
Chief Executive Officer  
Pathway Health



Sonja Short MD, FAAP, FACP  
Advisory Committee Co-Chair  
Minnesota e-Health Advisory Committee  
Associate CMIO Ambulatory and Population Health  
M Health Fairview

## Appendices

### Appendix A: Minnesota e-Health Advisory Committee 2019-2020

#### Members

**Sonja Short**, MD, *Advisory Committee Co-Chair*, Associate CMIO, M Health Fairview  
Representing: Physicians

**Peter Schuna**, *Advisory Committee Co-Chair*, Chief Executive Officer, Pathway Health Services  
Representing: Long Term Care

**Alan Abramson**, PhD, Senior Vice President, IS&T and Chief Information Officer, HealthPartners Medical Group and Clinics  
Representing: Health System CIOs

**Sunny Ainley**, Associate Dean, Center for Applied Learning, Normandale Community College  
Representing: HIT Education and Training

**Karl Anderson**, Global Digital Health Senior Manager, Medtronic  
Representing: Vendors

**Laurie Beyer-Kropuenske**, JD, Director, Community Services  
Representing: Minnesota Department of Administration

**Jennifer Fritz**, MPH, Director, Office of Health Information Technology  
Representing: Minnesota Department of Health

**Cathy Gagne**, RN, BSN, PHN, St. Paul-Ramsey Department of Public Health  
Representing: Local Public Health

**Steve Johnson**, PhD, University of Minnesota Academic Health Center  
Representing: Academics and Clinical Research

**George Klauser**, Executive Director, Altair-ACO, Lutheran Social Services  
Representing: Social Services

**Patricia K. Lang**, Consumer Advocate  
Representing: Consumers

**Jennifer Lundblad**, PhD, President and Chief Executive Officer, Stratis Health  
Representing: Quality Improvement

**Bobbie McAdam**, Vice President, Information Technology, Medica  
Representing: Health Plans

**Jeyn Monkman, MA, BSN, NE-BC**, Institute of Clinical Systems Improvement  
Representing: Clinical Guideline Development

**Lisa Moon**, PhD, RN, CEO Advocate Consulting  
Representing: Nurses

**Heather Petermann**, Division Director, Health Care Research & Quality, Minnesota Department  
of Human Services  
Representing: Minnesota Department of Human Services

**James Roeder**, Vice President of IT, Lakewood Health System  
Representing: Small and Critical Access Hospitals

**Jonathan Shoemaker**, Chief Information Officer, Allina Health  
Representing: Large Hospitals

**Steve Simenson**, BPharm, FAPhA, President and Managing Partner Goodrich Pharmacy  
Representing: Pharmacists

**Adam Stone**, Chief Privacy Officer, Secure Digital Solutions  
Representing: Expert in HIT

**Meyrick Vaz**, Vice President - Strategic Market Partnerships, UnitedHealthcare Office of the CIO  
Representing: Health Plans

**Sandy Zutz-Wiczek**, Chief Operating Officer, FirstLight Health System  
Representing: Community Clinics and FQHCs

**Vacant seats:**

Minnesota Department of Commerce  
Health Care Administrators  
Health Care Purchasers and Employers

## Designated Alternates

**Mark Jurkovich**, DDS, MBA, Dentist, Gateway North Family Dental  
Representing: Dentists

**Maiyia Kasouaher**, PhD, Community Engagement Lead, Program in Health Disparities Research,  
University of Minnesota  
Alternate Representing: Consumers

**Paul Kleeberg**, MD, Medical Director, Aledade  
Alternate Representing: Physicians

**Justin McMartin**, Senior Product Analyst, Surescripts LLC  
Alternate Representing: Vendors

**James Dungan-Seaver**, Health Information Exchange Architect, PrimeWest Health  
Alternate Representing: Expert in HIT

**Charles Peterson**, President and CEO, The Koble Group  
Alternate Representing: Vendors

**Mark Sonneborn**, Vice President, Information Services, Minnesota Hospital Association  
Alternate Representing: Hospitals

**Susan Severson**, CPEHR, CPHIT, Vice President, Health Information Technology, Stratis Health  
Alternate Representing: Quality Improvement

**Rui Zhang**, PhD, Associate Professor, Institute for Health Informatics, University of Minnesota  
Alternate Representing: Academics and Clinical Research

## **Appendix B: Opioid and e-Health Report: Summary of the 2017 Minnesota e-Health Advisory Committee's Opioids and e-Health Recommendations**

### **Introduction**

In response to the opioid epidemic, Governor Dayton requested the Minnesota e-Health Advisory Committee provide a set of recommendations for using e-health to prevent and respond to opioid misuse and overdose. The advisory committee, with input from the Opioids and e-Health Steering Team and Minnesota Department of Health, Office of Health Information Technology (OHIT), developed seven recommendations. The advisory committee believes implementation of the recommendations can have a significant impact on mitigating the opioid epidemic. OHIT developed this report to summarize the approach, recommendations and next steps of the advisory committee's work on opioids and e-health.

### **Approach**

The approach initially focused on the collection, use, and sharing of information necessary for the electronic prescribing of controlled substances (Figure 1) as requested by the advisory committee. With the request from Governor Dayton and input from the community, the scope was broadened to include additional uses of e-health to prevent and respond to opioid misuse and overdose. The following activities were critical to the development of the recommendations and building greater understanding of using e-health to prevent and respond to the opioid epidemic.

### **Minnesota Environmental Scan**

Prescribers, payers, pharmacies and state agencies provided information and perspectives regarding the electronic health care information needed to address the opioid epidemic. The interviews focused on two areas including:

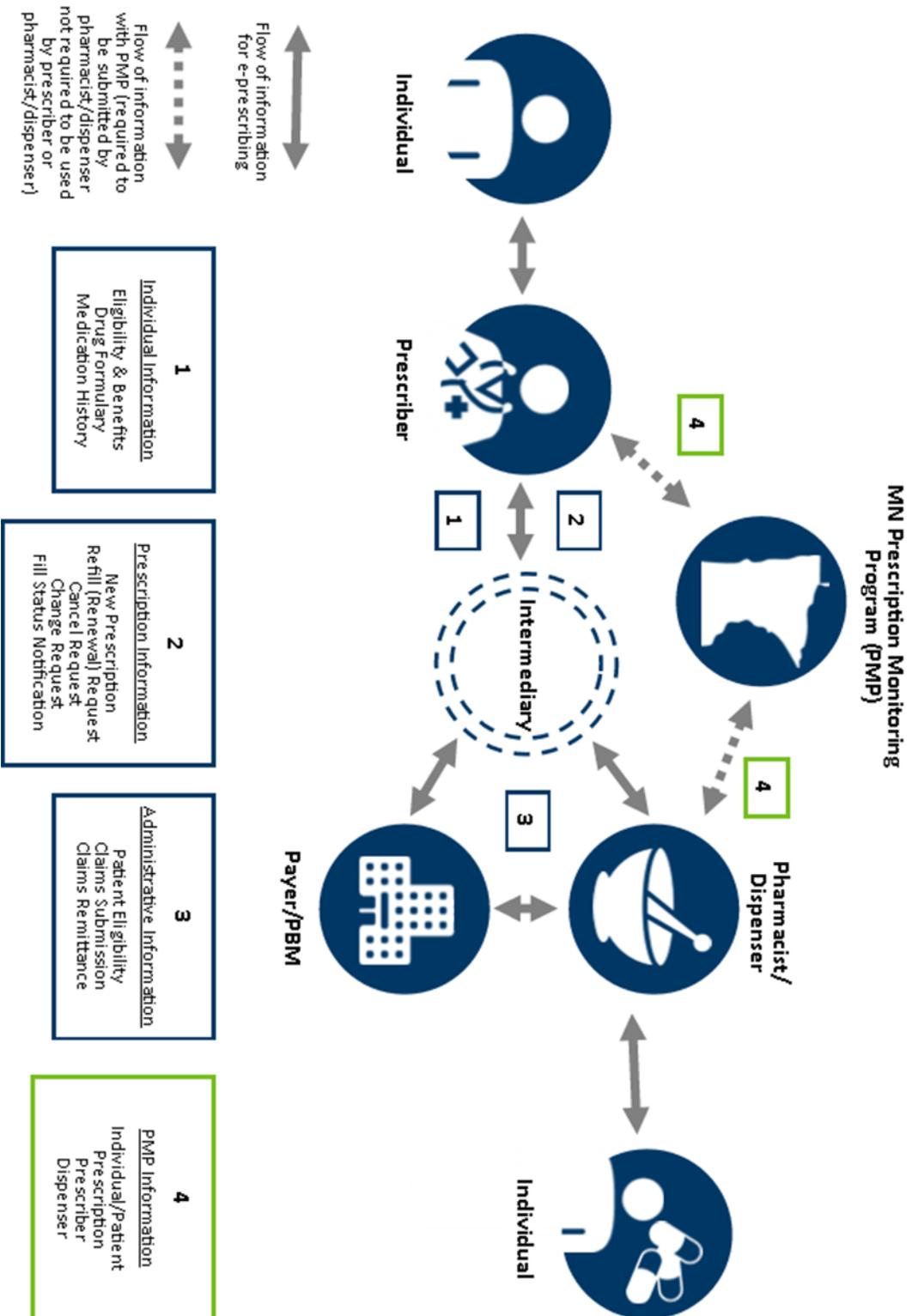
1. Whether and how such information is or could be exchanged via the types of data exchange subject to MN 62J.536 and 62J.495-4982; and
2. Any possible issues or constraints associated with the standard, electronic exchange or use of information needed to address the epidemic and how they might be addressed.

### **Engaging Partners and Collecting Input during the Minnesota e-Health Summit**

During the 2017 Minnesota e-Health Summit's, 'Leveraging e-Health to Prevent and Respond to Opioid Misuse and Overdose' session approximately 30 participants from across the care continuum shared feedback on:

- Preferred/recommended data sources;
- How information can best be provided/communicated via standard, electronic health business transactions and electronic health records;
- How electronic health data can be leveraged to help address the opioid epidemic;
- Key obstacles/challenges to providing/communicating the needed information; and
- Changes/solutions needed to address the challenges/obstacles.

**Figure 1. Common Information Flow for Electronic Prescribing of Controlled Substances**



## Nationwide Scan of Strategies Implemented by States to Address Opioid Epidemic

The scan obtained information about other states' legislative and policy strategies for addressing the epidemic. Key words used in the review included: "opioids," "EPCS" (electronic prescribing of controlled substances), "prescription monitoring program/prescription drug monitoring program," (PMP/PDMP) "medical cannabis," and "individual/patient education."

### Opioids and e-Health Steering Team

The Opioids and e-Health Steering Team provided input to the Advisory Committee on recommendations and strategies for using e-health to prevent and respond to opioid misuse and overdose. The participants of the Steering Team included experts in prescribing and dispensing controlled substances, e-prescribing controlled substances, and the Minnesota Prescription Monitoring Program. The Steering Team met twice and shared their perspectives and experiences during numerous advisory committee and public meetings.

## Recommendations

The advisory committee believes implementation of the following recommendations can have a significant impact on mitigating the opioid epidemic.

The advisory committee recommends that:

1. By July 2018, the Minnesota Legislature should provide resources to fully implement and ensure compliance with Minnesota Statutes Section 62J.497 including a focus on increasing the rate of e-prescribing of controlled substances from approximately 20 percent (Surescripts 2016 National Progress Report) to over 80 percent by 2020. Implementation of this recommendation should occur with input from the Minnesota e-Health Advisory Committee to:
  - a. Provide or ensure statewide education and technical assistance on electronic prescribing (e-prescribing) of controlled substances.
  - b. Support full-implementation of all e-prescribing related transactions in the nationally recognized National Council for Prescription Drug Programs Standards (NCPDP), including electronic prior authorization and Formulary and Benefits.
  - c. Provide grants to increase the rate of e-prescribing of controlled substances. Grantees include, but are not limited to, prescribers that serve rural or underserved populations; prescribers that have small, independent practices; and other providers needing support such as dentists.
  - d. Support the use of evidence-based clinical guidelines and clinical decision support.
  - e. Monitor the status of e-prescribing, specifically for controlled substances, and assess the barriers to e-prescribing of controlled substances.
  - f. Develop and implement policy options including rulemaking and enforcement for non-compliance of e-prescribing as needed, if goals are not met.
2. By January 2019, the Minnesota Board of Pharmacy, with input from the Minnesota e-Health Advisory Committee, health and health care provider associations, and other stakeholders, should develop requirements and an implementation plan to improve the Prescription

Monitoring Program (PMP). The requirements and implementation plan should include use cases and policies for the required use of the PMP. The implementation plan should:

- a. Address affordable, effective and seamless use of the PMP by prescribers and dispensers through the EHR, other HIT, and integration into Minnesota's HIE and include full implementation of clinical guidelines and clinical decision support and access to other states' PMP information.
- b. Improve stakeholder input and oversight, representative governance, regulatory authority, and funding of the PMP to support alignment with state and federal requirements and standards, improve data quality and usability, support patient consent and privacy, and meet workforce-training needs.

The Governor and Legislature should appropriate funds for the development and implementation of the requirements and implementation plan to improve the PMP.

3. By July 2018, the Minnesota Legislature should amend Minnesota Statutes, Section 152.126 to expand the permitted uses of Prescription Monitoring Program data. The updated language should ensure that state and federal agencies, tribal governments, academia, local public health, payers, and other partners are able to appropriately access and analyze information for improved prevention, response, and care while safeguarding patient privacy in accordance with state and federal law. Transparent processes and principles developed by the Board of Pharmacy with input from the Minnesota e-Health Advisory Committee and other stakeholders should guide access to the Prescription Monitoring Program data. Potential data uses should include, but are not limited to:
  - a. Identify geographic areas and populations showing indicators of misuse and abuse to better target resources for prevention, response, and coordinated care, treatment, and services.
  - b. Ensure more timely and accurate responses to misuse and overdoses by leveraging other data sources such as overdose, toxicology, and drug seizure reports; medical examiner/coroner data; payer claims; poison control reports; and birth and death records.
  - c. Support the development and use of advanced clinical decision support and clinical guidelines to flag suspicious behavior and/or patterns and identify individuals at risk for opioid misuse at the point of care and beyond.
  - d. Identify critical needs for training and best practices for prescribers, dispensers and other providers such as emergency medical services and local public health.

The Governor and Legislature should appropriate funds to support the expanded uses of the Prescription Monitoring Programs data, and develop and implement the transparent processes and principles to guide access to data.

4. State agencies and associations should, by September 2018, review, update, and provide education on e-health and opioids policies and guidelines to ensure dispensers, prescribers, payers, and other providers, including the care team, have appropriate and timely access to health information, can subsequently share information, and understand their scope of action

related to the information. Use cases should include, but are not limited to, instances when prescribing and dispensing practices are outside nationally recognized clinical guidelines, such as those published by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration, and individuals are at-risk for misuse and abuse.

5. The Governor, by July 2018, should ensure access and coverage for all Minnesotans and providers, and provide resources for grants and technical assistance, to expand access to services and care enabled by telehealth, telemedicine and other forms of virtual technology to fill access gaps in opioid tapering and withdrawal, chemical dependency, mental health, and alternative pain treatment and services.
6. The Governor should support state agencies and stakeholders in participating in statewide coordinated HIE services. The support should be consistent with the findings of Minnesota Health Information Exchange Study, which will be submitted to the Legislature in February of 2018, align with input from the Minnesota e-Health Advisory Committee, ensure providers and public health have access to information to support individual and community health services, and support:
  - a. Alerts for emergency services, urgent care, and other medical visits relating to substance misuse and overdose.
  - b. Referrals to substance abuse treatment and community services.
  - c. Access to patient health history including medication lists.
7. The Minnesota Department of Health, by December 2018, should submit to the Governor and the Legislature an update to their informatics profile that assesses the gaps in current information and information systems used to prevent and respond to substance misuse and overdose and identify resources needed to fill those gaps. The Governor and Legislature should appropriate funds to ensure those needs are met.

The advisory committee also recognized that mitigating the opioid epidemic goes beyond e-health. There is a need for better access to and coverage for health services, specifically opioid tapering and withdrawal, chemical dependency, mental health and alternative pain treatment and services. Therefore, they also recommend the Governor work to ensure all Minnesotans have access to the treatment and services needed to achieve health and wellbeing.

## Next Steps

The advisory committee and its stakeholders will continue to prioritize work to mitigate the opioid epidemic. In the coming months, it will move forward with the findings of the legislatively mandated study on HIE, which improves the seamless flow of information to prescribers and dispensers. It will continue to monitor and provide input into state and national activities regarding e-prescribing of controlled substances, Prescription Monitoring Program, and related issues.