August 13, 2019

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Submitted electronically at: https://www.regulations.gov/comment?D=CMS-2019-0090-0001

Attention: Public Comment Medicare Program: Secure Electronic Prior Authorization for Medicare Part D Proposed Rule

Centers for Medicare & Medicaid Services:

Thank you for the opportunity to provide input on Medicare Program: Secure Electronic Prior Authorization for Medicare Part D Proposed Rule. 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, Office of Health Information Technology, coordinates activities of the Initiative.

The Advisory Committee recognizes the need to implement electronic prior authorization to support clinical best practices and improved patient experiences. We support requiring use of a single standard, the NCPDP SCRIPT Standard Version 2017071 electronic prior authorization (ePA) transactions, for Part D-covered products prescribed to Part-D eligible individuals. This proposed rule is consistent with Minnesota's statutory requirements, and with our 2017 recommendations to the Governor of Minnesota to 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 (see Appendix B).

However, we even more strongly support adopting the standard for patients of all types of insurance coverage and for all products covered under the pharmacy benefit. The use of two different standards would be overly burdensome for the prescribers, creating dual workflows and new inefficiencies.

We are concerned about the negative impact on Minnesota's small and/or specialty organizations that use an array of EHR systems and have fewer resources to manage technical upgrades. Minnesota's health care and technology landscape has a wide variety EHR and other systems in use, including:

- 129 non-federal acute care hospitals using 8 different EHR systems.
- 1,500 primary and specialty care clinics using more than 40 different EHR systems.
- 7 local commercial health plans, multiple national commercial health plans, 3 county-based purchasing organizations, and 1 state-based purchaser.
- Up to 18 different pharmacy benefit managers serving the Minnesota market.

We are also concerned that the use of two different standards will have a negative impact on patients. Prescribers would need to follow a different, less efficient, prior authorization workflow for patients who are not Part D beneficiaries. Further, patients who utilize multiple sources of payment may experience delays in authorization for their non-Part D medications.

Finally, we recommend extending the implementation timeframe to at least 24 months from the date of the final rule to allow for technical and workflow implementation. We believe this to be consistent with industry recommended best practices.

Please consider these comments and recommendations related to the Medicare Program: Secure Electronic Prior Authorization for Medicare Part D Proposed Rule. They are developed from input from across Minnesota and work of the Initiative. Contact Karen Soderberg, Supervisor, e-Health and Health Information Exchange, Office of Health Information Technology, Minnesota Department of Health at karen.soderberg@state.mn.use with any questions.

Sincerely,

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Peter Schuna
Advisory Committee Co-Chair
Minnesota e-Health Advisory Committee
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Sonja Short MD, FAAP, FACP
Advisory Committee Co-Chair
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Appendices

Appendix A: Minnesota e-Health Advisory Committee 2018-2019

Members

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

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

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

Constantin Aliferis, MD, MS, PhD, FACMI, Chief Research Informatics Officer, University of Minnesota Academic Health Center
Representing: Academics and Clinical Research

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

Laurie Beyer-Kropuenske, JD, Director, Community Services Division
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

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

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

Peter Schuna, Chief Executive Officer, Pathway Health Services
Representing: Long Term Care
Co-Chair: Health Information Exchange Task Force

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

Donna Watz, JD, Deputy General Counsel, Minnesota Department of Commerce
Representing: Minnesota Department of Commerce

Ann Warner, Manager, Data Engineering, HealthEast
Representing: Health Care Administrators

John Whitington, Chief Information Officer, South Country Health Alliance
Representing: Health Care Purchasers and Employers

Ken Zaiken, Consumer Advocate, AARP Minnesota
Representing: Consumers

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

Designated Alternates

George Klauser, Executive Director, Altair-ACO, Lutheran Social Services
Alternate Representing: Social Services
Co-Chair: Health Information Exchange Task Force

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

Rochelle Olson, MPH, Systems Management Supervisor, Dakota County Public Health
Alternate Representing: Local Public Health

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

Appendix B: Opioid and e-Heath 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:

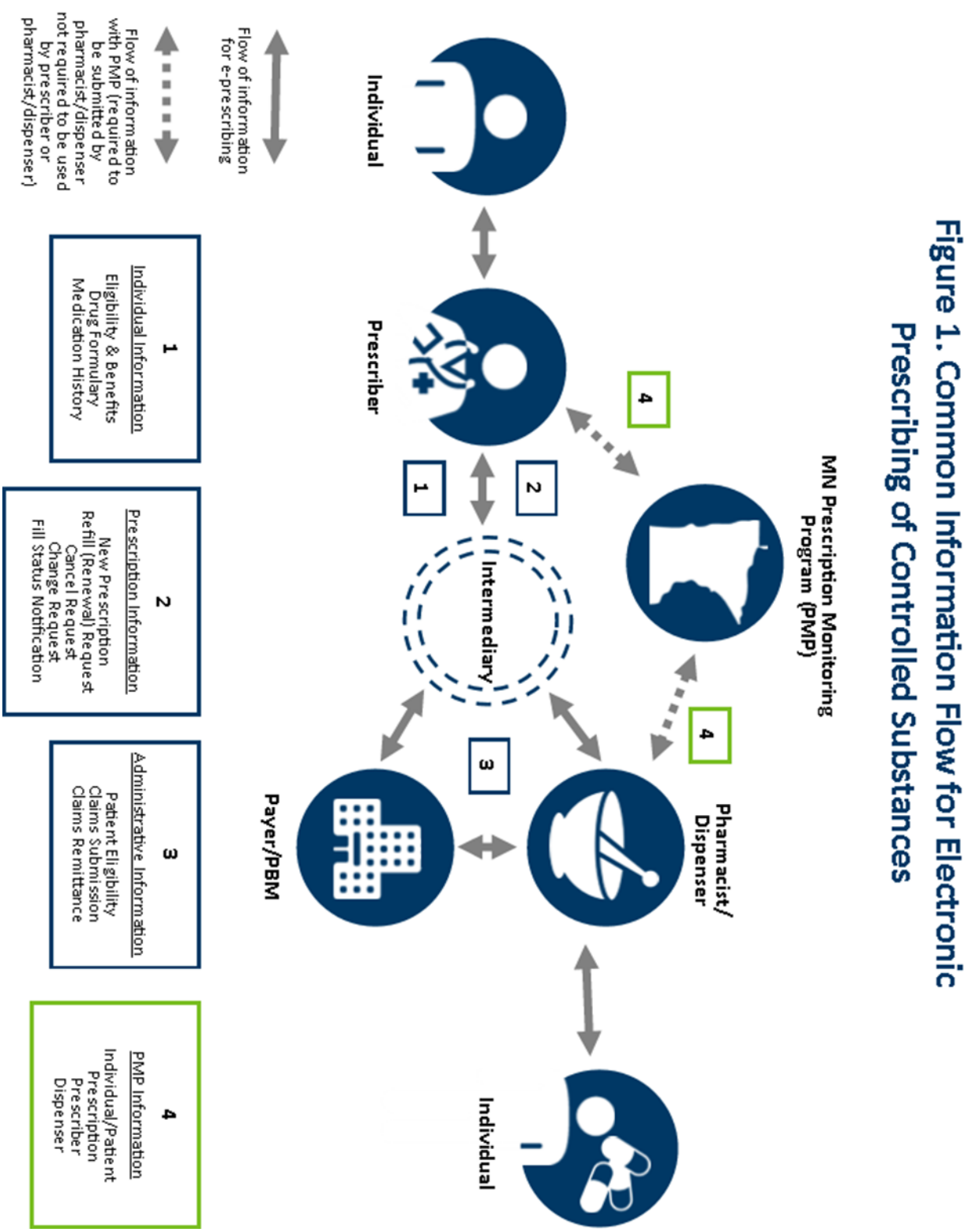
1. Whether and how such information is or could be exchanged via the types of data exchange subject to MN 62J.536 and 62J.495-4982; and
2. Any possible issues or constraints associated with the standard, electronic exchange or use of information needed to address the epidemic and how they might be addressed.

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.