May 29, 2015

Centers for Medicare and Medicaid Services
Department of Health and Human Services

Attention: Minnesota e-Health Initiative Statewide Coordinated Response to the EHR Incentive Program – Stage 3 NPRM

The Minnesota e-Health Initiative is pleased to submit comments on the EHR Incentive Program – Stage 3 NPRM. We appreciate the work done to date by CMS to advance e-health to improve individual and population health. Thank you for providing an opportunity to submit comments for your consideration. Should you have questions you may contact:

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The Minnesota e-Health Initiative Statewide Coordinated Response to the EHR Incentive Program – Stage 3 NPRM

Introduction and Approach

Minnesotan e-Health Advisory Committee
The Minnesota e-Health Advisory Committee is a 25-member legislatively-authorized committee appointed by the Commissioner of Health to build consensus on important e-health issues and advise on policy and common action needed to advance the Minnesota e-Health vision (Figure 1). The Committee is comprised of a diverse set of key Minnesota stakeholders, including: consumers, providers, payers, public health professionals, vendors, informaticians, and researchers, among others.

For the past eleven years the e-Health Initiative, led by the Minnesota e-Health Initiative Advisory Committee and the Minnesota Department of Health, Office of Health Information Technology (OHIT), has pushed for and supported e-health across the continuum of care; as a result, Minnesota is a national leader in implementation and collaboration. The committee co-chairs are Bobbie McAdam, Senior Director, Medica and Alan Abramson, Senior Vice President, HealthPartners. See Appendix A for a listing of current Advisory Committee Members.

Workgroups
Committee members participate in workgroups to dive into detailed topics such as privacy and security, health information exchange, and standards and interoperability. The workgroups are the primary vehicle for receiving public input and investigating specific e-health topics through discussion and consensus-building. Each workgroup has a charter declaring the purpose, schedule, deliverables, and co-chairs that guide the process. The co-chairs and workgroup participants contribute subject matter expertise in discussions, research, and analyses through hundreds of hours of volunteer time. OHIT staff facilitate, analyze and interpret data, and summarize findings that will contribute to e-health policy development. Workgroup participants are recruited statewide and are open to the public.

Statewide Coordinated Response Approach
This statewide coordinated response to the request for public comment invited multiple stakeholders, including the Advisory Committee and workgroups, from the Minnesota health and healthcare system to participate in two meetings and submit written comments. Nancy Garrett, Hennepin County Medical Center, and Paul Kleeberg, Stratis Health provided leadership as co-chairs of the response and OHIT coordinated the work.

The Initiative recognizes the value in providing statewide response to the NPRM. We identified areas needing more clarity or action in the comments and recommendations below. We strongly encourage consideration of these comments and recommendations.
General Comments and Recommendations

1. Patient access to their health information and engagement in their health and care needs to continue to be a priority. Unfortunately, it is easier for most consumers to get their medication list from retailers (e.g., Walgreens or Target) than their primary care doctor. We recommend CMS and ONC work together to assure that each objective and associated measures and standards (both EHR certification and the Standards Advisory) truly advances patient access and engagement and meets their needs.

2. There continues to be confusion for hospitals with internal pharmacies in the areas of e-prescribing and CPOE. We recommend on-going education and training is needed to assure best practices and workflows are being used to assure safe and effective medication prescribing and management.

3. As individuals continue to collect, use and share their data generated from Fitbits and other devices, CMS and ONC need to identify best practices, standards, and use for this data. Providers are not sure what to do with the data or even if it is relevant. There are not significant studies on consumer-generated data. We strongly recommend funding for studies to create better understanding on consumer-generated data use and how to best incorporate the information into EHRs to advance individual, population, and public health.

4. The Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap highlighted the importance of social determinants of health and health equity. This priority is not supported by Meaningful Use Stage 3. The topping out of the social determinants of health measures (demographics) and lack of alignment with the IOM recommendations on social determinants of health do not advance health equity. There is a need to build on the IOM report and achieve national consensus on the social determinants of health. We recommend that CMS, ONC and other federal partners reach national consensus on the social determinants of health – value sets, use, and standards. This discussion must include providers from across the care continuum and have strong consumer engagement.

Comments and Recommendations on Specific Provisions of the Proposed Regulations

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<td><strong>Meaningful Use Stages (pg. 28)</strong></td>
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| We propose a definition of meaningful use that would apply beginning in 2017. This definition of meaningful use, although referred to as "Stage 3", would be the only definition for the Medicare and Medicaid EHR Incentive Programs, and would incorporate certain requirements and aspects of Stages 1 and 2. | Comments  
1. EP and EH/CAH not starting Meaningful Use until 2017 will have many hurdles to get started.  
Recommendations  
1. We support and recommend the timeframe for Stage 3 but request that it start no sooner than 2018 due to the time required for HIT vendors to get certified EHRs rolled out and implemented. |
| • Beginning with 2018, we propose to require all EPs, eligible hospitals, and CAHs, regardless of their prior participation in the EHR Incentive Program, to satisfy the requirements, objectives, and measures of Stage 3. |                              |
| • However, for 2017, we propose that Stage 3 would be optional for providers. This option would allow for a provider to move on to Stage 3 in 2017 or remain at Stage 2, or for some providers to remain at Stage 1, depending on their participation timeline. |                              |
| **EHR Reporting Period (pg. 33)**           |                              |
| We are proposing to change the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" under § 495.4 for EPs, |                              |
| Comments  
1. We support all EP and EH/CAH reporting on a calendar year.  
2. There is concern about the CMS website managing the load |                              |

Proposed Program and Implementation Details

eligible hospitals, and CAHs such that the EHR reporting period would be one full calendar year, with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time (pg. 35)

Comments and Recommendations

of all EP and EH/CAH attesting in the same timeframe.
3. For independent providers and small health facilities with a hospital and a clinic, attesting within a two-month period may be unrealistic due to small or singular staffing.
4. For large health facilities, attesting within a two-month period may be unrealistic due to the number of providers and hospitals.

Recommendations

1. We strongly recommend CMS extend the 2-month attestation period to a 4-month period. This should alleviate the staffing burdens identified in the comments section.
2. We recommend the option of an extension if staffing or the CMS website prevents attestation.
3. We recommend all EP and EH/CAH report on a calendar year.

Topped Out Measures (pg. 43)

While the EHR Incentive Program does not use a benchmarking system to rate the overall and relative performance of providers as part of the definitions of meaningful use; we are proposing to adopt an approach to evaluate whether objectives and measures have become "topped out" and, if so, whether a particular objective or measure should be considered for removal from reporting requirements.

Comments

There are many about topped out measures including:
1. Cons
   a. Performance may fall if measures are not measured.
   b. Not everyone is currently achieving the topped out measures, as some are menu options in Stage 2. Those achieving the menu options may have chosen them because they were able to do them well. This does not mean everyone can do or will do them well.
   c. Removing the measures may lead to EHR vendors not providing metrics on the measures.
   d. These measures are used for benchmarking and internal quality improvement work.
2. Pros
   a. Some topped out measure are part of workflow, policies, and best practices.
3. The topped out measures are necessary for patient-centric care, transitions of care, health equity, the learning health system, quality improvement, and measuring and achieving outcomes.

Recommendations

1. We recommend all topped measures be required for EP and EH/CAH but not measured for a threshold. Therefore, the measure would be to have this information and be able to track. This will support good practices for patient-centric care, transitions of care, health equity, the learning health system, quality improvement, and measuring and achieving outcomes.

Electronic Versus Paper-based Objectives and Measures (pg. 45)

For Stage 3, we propose to discontinue the policy of using non-electronic format or action to meet at

Comments

1. This may eliminate the drive to provide information to a patient or another provider in a format that they prefer. We should be measuring whether or not patients and other
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<td>measure. (pg. 46)</td>
<td>providers are getting information in the format they prefer. This is of particular concern for providers who serve rural areas (inadequate Internet access) and populations that have lower penchant for using electronic tools (e.g., elderly, institutionalized).</td>
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**Recommendations**
1. We recommend supporting and measuring if the patient or other providers are getting information in their preferred format.

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<th>Eps Practicing in Multiple Practices/Locations (pg. 52)</th>
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<td>For Stage 3, we propose to maintain the policy from the Stage 2 final rule (77 FR 53981) which states that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. (pg. 52)</td>
<td>1. We recommend the continuation of this policy.</td>
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<th>Patient-Authorized Representatives (pg. 58)</th>
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<td>In the Stage 3 Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective outlined in section II.A.1.c.(2),(i) of this proposed rule, we propose the inclusion of patient-authorized representatives in the numerators as equivalent to the inclusion of the patient. • We recognize that patients often consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make health care decisions. • Accordingly, as part of these objectives, we encourage providers to provide access to health information to patient-authorized representatives in accordance with all applicable laws.</td>
<td>1. We recommend the inclusion and engagement of patient-authorized representatives. 2. We recommend the development of best practices on how to best measure/count patient-authorized representatives. 3. We recommend the development and sharing of best practices on strategies to effectively engage patient-authorized representatives to assure we are changing outcomes, not just counting numbers.</td>
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<th>Certified EHR Technology (CEHRT) Requirements (pg. 152)</th>
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<td>CMS proposes to take a different approach under which CMS would define the term &quot;Certified EHR Technology,&quot; and that definition would be specific to the EHR Incentive Programs. (pg. 154) • The CEHRT definition would include the 2015 Edition Base EHR definition and have other important capabilities (pg. 157) • CMS would establish through rulemaking for the EHR Incentive Programs (either with stand-alone rulemaking or through other vehicles such as the annual Medicare payment rules) the compliance dates by which providers must use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition, which would be reflected in our regulations under 42 CFR part 495 rather than ONC's regulations under 45 CFR Part 170.</td>
<td>1. We have concerns about how this will implemented and communicated to EP and EH/CAH. 2. Providers will need to know that 2015 Edition Base EHR is not enough to meet Meaningful Use. 3. How will CMS and ONC assure/work to prevent fraudulent/misleading advertising by EHR vendors?</td>
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**Recommendations**
1. We recommend CMS and ONC develop clear and concise communication materials about this change.
2. We recommend CMS and ONC develop a process to address fraudulent/misleading advertising or practices by EHR vendors.
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| **Protect Patient Health Information:** Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards. (pg. 63) | **Comments**
1. Completing a security risk analysis is not enough to achieve changes in outcomes. Doing an effective security risk analysis, including risk mitigation, is how we change outcomes.
2. There is need to provide education and best practices on conducting an effective security risk analysis with risk mitigation.
3. Meaningful Use has been successful increasing the awareness of risk analysis.
4. There needs to be more clarity on when a risk analysis would need to be refreshed. Is it with every update grade or patch to address a bug? |
| **Measure:** Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a) (1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a) (2) (iv) and 45 CFR 164.306(d) (3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. (pg. 63) | **Recommendations**
1. We recommend training and support for providers and organizations across the care continuum to conduct risk analysis and mitigate risk.
2. We recommend more detail guidance on when a risk analysis needs to be completed/refreshed.
3. We recommend including this objective and measure. |
| **Electronic Prescribing:** EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx). (pg. 67) | **Comments**
1. There is a need to provide clarity on internal pharmacies and their role in the EH/CAH measure.
2. We support excluding OTC from the definition of the prescription but it is important that OTC be on the medication list.
3. For pediatrics, there is also a concern related to transmission of patient weight, which is not part of the standard transaction for e-prescribing. This is affecting workflow with e-prescribing, as pharmacy follow up is required, especially in pediatric environment when much of dosing is based on weight. NCPDP and HISPs have no place in specifications to add a weight, which is a pediatric issue.
4. We support moving toward managing controlled substances electronically, but the technology to support this needs to be efficient in supporting process. Currently, with separate workflows for controlled versus uncontrolled substances, we find many providers default to printing if the prescription includes both types of drugs.
5. There are issues with inclusion of state-specific controlled substances being included in reporting (i.e., growth hormone is considered a controlled substance in MN). |
| **EP Measure:** More than 80% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. (pg. 70) | **Recommendations**
1. We recommend the option of e-prescribing of controlled substances and recognize this may be a financial burden (transaction-based and system upgrades) on prescribers, pharmacists and other stakeholders.
2. We do not recommend requiring hospitals to distinguish refills from new or altered prescriptions. |
| **Eligible Hospital/CAH Measure:** More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT. (pg. 72) | **Recommendations**
1. We recommend the option of e-prescribing of controlled substances and recognize this may be a financial burden (transaction-based and system upgrades) on prescribers, pharmacists and other stakeholders.
2. We do not recommend requiring hospitals to distinguish refills from new or altered prescriptions. |
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#### Clinical Decision Support: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions. (pg. 75)

**Measures:** EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective (pg. 77):

**Measure 1:** Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

**Measure 2:** The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

#### Computerized Provider Order Entry: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines. (pg. 81)

**Measures:** An EP, eligible hospital, or CAH must meet all three measures. (pg. 85)

**Measure 1:** More than 80% of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

**Measure 2:** More than 60% of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or ED (POS 21 or

### Comments and Recommendations

| 3. | We recommend CMS, ONC, NCPDP, and HIE service providers work to address the gap of patient weight in e-prescribing to improve workflow and reduce patient safety issues. |
| 4. | We recommend ongoing resources, education, and best practices development to address issues with e-prescribing controlled substances and take into consideration state-specific controlled substances. |

#### Comments

1. CQMs do not always align with best practices.

2. There are concerns about the timing of releasing/announcing new, updated, or retired CQMs. What happens if one of your CDS interventions is related to a CQM that is changed?

3. There is a need for more education around this objective and associated measures.

#### Recommendations

1. We recommend a process “grandfathering” in for a year if a CQM change causes a fail of Measure #1.

2. We recommend continued alignment at the national level of CQMs to support the learning health system, transitions of care, and health equity. The alignment should include CQMs from across the continuum of care.

3. We recommend education so EP and EH/CAH understand that the CDS may align with health priorities if CQMs do not fall into the scope of practice.

#### Comments

1. There needs to be more clarity and education on CPOE and pharmacy orders for EH/CAH. For example, should medication orders entered by a pharmacist into the pharmacist system count towards measure 1?

#### Recommendation

1. We recommend measures 1-3 and support the expansion of radiology orders to imaging orders to address the needs of specialists and allow for a wider variety of clinical orders.
### Proposed Program and Implementation Details

23) during the EHR reporting period are recorded using computerized provider order entry; and

**Measure 3:** More than 60% of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital’s or CAH’s inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

While our experience with both Stage 1 and Stage 2 of meaningful use has shown that a denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers and would create a better measurement for CPOE usage, particularly for EPs who infrequently order medications, this does not guarantee such a denominator would be feasible for all providers. We invite comments on whether to continue to allow, but not require, providers to limit the measure of this objective to those patients whose records are maintained using CEHRT. (pg. 87)

### Comments and Recommendations

**Recommendation**

1. We recommend not maintaining the distinction, as it is not necessary.

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### Patient Electronic Access to Health Information:

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability. (pg. 94)

**Measures:** EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective: (pg. 96)

**Measure 1:** For more than 80% of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23):

1. The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

2. The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

**Measure 1 Comments**

1. It is important that individuals have access to their health information but there are workflow and other issues that require attention and clarity.

2. What is the definition of “of its availability”? Is 24 hours for the business week? How are weekends accounted in this timeframe?

3. The use of API has financial burdens on the EP and EH/CAH. Just because there are free or low cost API solutions does not mean the EHR vendor will support them.

4. There are concerns and unknowns around reliability, completeness, and quality of data received from solutions that leverage APIs.

5. There are concerns around the ease of retrieval of information via APIs, its impact on workflows, and understanding of APIs and the products that leverage APIs.

6. Let the EP and EH/CAH patient population decide if API is what they want. Do not require financial investments unless it meets the needs of the patients. CMS clearly states, “patient access to health information should be provided in a manner requested by the patient”.

7. There are issues around non-English language speakers English as a second language that need to be addressed for portals, electronic communication, and health education materials.

8. There are issues around establishing or identifying legal guardianship that affect access to the patient portal and electronic communication.

**Measure 1 Recommendations**

1. We recommend view, download, and transmit within 24 hours but are concerned that only having an API option will create another accessibility issues. “Availability to the
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<td>provider” needs to be defined and the 24-hour timeframe needs to be specified in terms of business operating hours.</td>
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<td>2. We recommend and encourage development of API uses, best practices, and standards development.</td>
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<td>3. We recommend development of resources, education, and best practices to address portal issues around availability of non-English languages and legal guardianship.</td>
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<td>4. We recommend adding an exclusion for patients who require establishment of legal guardianship. For some specialty providers, such as pediatrics, this is a necessary exclusion.</td>
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### Patient Electronic Access to Health Information:

**Measure 2:** The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period.

### Measure 2 Comments

1. It is important to recognize that not all patients want information electronically.
2. This measure is not patient-centric.
3. How is this measure counted when the patient education software is not CEHRT? It is not unusual for patient education software to be separate from the EHR.

### Measure 2 Recommendations

1. We recommend measure 2 with the following change “and provide electronic, **paper or other access** to those materials”.
2. We recommend ONC, CMS and other partners advance the customization of patient information, assuring the patient gets the right and requested information.

### Coordination of Care through Patient Engagement:

**Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care. (pg. 105)**

**Measures:** We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective. (pg. 106)

### Recommendations

1. We recommend EH/CAH meet 1 of 3 measures and EP meet 2 of 3 measures AND
2. We recommend EH/CAH and EP be required to report on all three measures. This information should be publicly available to foster improvement and drive best practices.

### Coordination of Care through Patient Engagement:

**Measure 1:** During the EHR reporting period, more than 25% of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:

1. More than 25% of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

### Measure 1 Comments

1. There are many factors as to why a person will or will not use a portal or engage with the EHR made accessible by the provider including: internet/computer literacy; health status; health literacy; language preference; learning style/preference; internet access speed, and cost; and preference for paper.
2. Many EP and EH/CAH have not met MU2 objective on view, download, and transmit making the threshold of 25% for MU3 too high.
3. There are concerns that the standards to support the use of ONC-certified API are still under development and are not yet mature enough to be included in regulation.
4. Any view, download and transmit during the reporting period, including during a hospital stay, would count
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<td>(2) More than 25% of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.</td>
<td>toward the numerator. For EH, much of the portal or access benefit is during the visit, especially for patient families of pediatric or neonatal patients.</td>
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**Measure 1 Recommendations**

1. We recommend a threshold of 25% if patients that opt out of participating in a patient portal be excluded from the denominator; OR if the exclusion is not expanded, we recommend a threshold of 5% to 10%.

2. We recommend the use of an API remain optional but the ONC and CMS should provide funds to encourage API and develop best practices.

3. We recommend that view, download, or transmit during the patient stay be included in the threshold for EH/CAH.

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**Coordination of Care through Patient Engagement:**

**Measure 2:** For more than 35% of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).

**Measure 2 Comments**

1. Patients discharged from the hospital should be communicating with primary care provider rather than the hospital.

2. This measure requires workflow and policies changes and redesign.

3. The definition of care team members needs to be defined. Any provider who contributes to patient-centered communication via a secure messaging should receive credit for the communication - the point is to improve collaboration, regardless if first or last provider to comment.

**Measure 2 Recommendations**

1. We recommend this measure is optional for EH/CAH as patients should be communicating with primary care provider after discharge.

2. We recommend a 10-15% threshold for EP with a denominator of only patients signed-up with a portal.

3. We recommend any provider who contributes to the patient-centered communication should receive credit toward the measure.

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**Coordination of Care through Patient Engagement:**

**Measure 3:** Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15% of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period.

**Measure 3 Comments**

1. This measure contains two separate concepts: patient-generated data vs. non-clinical data.

2. There are issues, real and perceived, about patient-generated data including data accuracy/quality, use, possible security threats, standardization, and others.

3. There are issues, real and perceived, about incorporating other providers’ data including use, data accuracy/quality, and trust.

4. There are concerns that the standards to support the use of patient-generated data are still under development and are not yet mature enough to be included in regulation.

**Measure 3 Recommendations**

1. We recommend removing non-clinical data from measure #3 as it will be addressed in the Health Information
## Proposed Program and Implementation Details | Comments and Recommendations
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| Exchange measures. 2. We recommend measure #3 as: Patient-generated health data is incorporated into the certified EHR technology for more than 15% of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period. 3. We recommend not using rulemaking to define how to incorporate patient generated data as standards and best practices are not yet mature enough to be included in regulation. |

### Health Information Exchange:

**Measure 1:** For more than 50% of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- **Measure 1 Comments**
  1. There is a need to increase the exclusion options.
  2. There is concern about increasing the threshold for summary of care documents sent electronically from 10 percent in Stage 2 to 50 percent for Stage 3 as providers are experiencing difficulties meeting the current threshold due to the lack of readiness or capacity on the part of clinicians to whom they would send the summary of care record and EHR capacity.
  3. There are situations where other providers cannot receive summary of care electronically

- **Measure 1 Recommendations**
  1. We recommend including Measure 1 but either include exclusion options for EP and EH/CAH that have limited electronic exchange partners (e.g., the only nursing home in the community does not or cannot take summary of care records electronically); OR lower the threshold to 20-25%.

**Measure 2:** For more than 40% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

- **Measure 2 Comments**
  1. This is very dependent on the capacity and actions of other providers.
  2. It is difficult to define/determine “never encountered before”. What if the patient was not seen in 5 years? 10 years?
  3. It will require extra analyst time to determine the “not seen before” population.

- **Measure 2 Recommendations**
  1. We recommend tracking for all transitions and referrals but not using a threshold. This information should be publicly available to foster improvement and drive best practices.

**Measure 3:** For more than 80% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- Medication. Review of the patient's medication,
## Proposed Program and Implementation Details

including the name, dosage, frequency, and route of each medication.
- Medication allergy. Review of the patient's known allergic medications.
- Current Problem list. Review of the patient's current and active diagnoses.

## Comments and Recommendations

5. This measure has far too many questions, indicating that it is not ready to be a rule with a required threshold. Rather we recommend recording and making the data discoverable.

### Measure 3 Recommendations

1. We recommend that clinical information reconciliation occur based on best practices.
2. We recommend that EPs can continue to define all encounters as “relevant” and choose to count them in the denominator.
3. We recommend tracking completed reconciliations, but not to have a threshold. This information should be publicly available to foster improvement and drive best practices.

## Public Health and Clinical Data Registry Reporting

**Reporting:** The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice. (pg. 136)

**Measures:** We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. As noted, measures four and five for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available. (pg. 138)

## Comments

1. The measures of Objective 8 need to build off Stage 2 meaningful use. Therefore, Immunization Registry Reporting and Electronic Reportable Laboratory Results should continue to be required.
2. Providers are confused about the differences between Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.
3. Public Health Agencies are lacking resources and support in the areas of updating information systems, onboarding, and staff training.

## Recommendations

1. We recommend Immunization Registry Reporting measure be required for all EP and EH/CAH with the proposed exclusions.
2. We recommend the Electronic Reportable Laboratory Results measure be required for all EH/CAH with the proposed exclusions.
3. We recommend EP and EH/CAH be in active engagement with a public health agency for two measures from Syndromic Surveillance, Case Reporting, and/or Public Health Registry Reporting. This can be achieved from any combination of measures such as two Public Health Registry Reporting measures or one Syndromic Surveillance measure and one Case Reporting measure.
4. We recommend for EP or EH/CAH whose scope of work is outside the Public Health Registry Reporting measures, or if the public health agency is not capable of receiving the Public Health Registry Reporting measures, submit to at least one Clinical Data Registry Reporting measure.
5. We recommend removing the option of reporting directly to the CDC for Public Health Registry Reporting measures. It is necessary that all public health reporting be coordinated with the Public Health Agency.
6. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information
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<td><strong>Public Health and Clinical Data Registry Reporting</strong></td>
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| **Measure 1:** Immunization Registry Reporting (Measure can count only 1 time for both EP and EH/CAH) The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS) (pg. 140) | **Comments**
1. The measures of Objective 8 need to build off Stage 2 meaningful use. Therefore, Immunization Registry Reporting and Electronic Reportable Laboratory Results should continue to be required.  
2. We support the addition of “bi-directional”. This provides a significant value for providers and patients alike. The ability to receive the information that is stored for any location that participates as well as the CDS for immunization recommendations will improve care.  

**Recommendations**
1. We recommend Immunization Registry Reporting measure be required for all EP and EH/CAH with the proposed exclusions.  
2. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information systems, support onboarding process, and provide staff training. |
| **Public Health and Clinical Data Registry Reporting** |                                  |
| **Measure 2:** Syndromic Surveillance Reporting (Measure can count only 1 time for both EP and EH/CAH) The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23). (pg. 142) | **Comments**
1. Minnesota, like some other states, does not support Syndromic Surveillance given the limited public health value for the investment.  

**Recommendation**
1. We recommend EP and EH/CAH be in active engagement with a public health agency for two measures from Syndromic Surveillance, Case Reporting, and/or Public Health Registry Reporting. This can be achieved from any combination of measures such as two Public Health Registry Reporting measures or one Syndromic Surveillance measure and one Case Reporting measure. |
| **Public Health and Clinical Data Registry Reporting** |                                  |
| **Measure 3:** Case Reporting (Measure can count only 1 time for both EP and EH/CAH) The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. (pg. 143) | **Comments**
1. There are numerous workflow and implementation issues to address for Case Reporting.  
2. The standards for Case Reporting need to mature and more pilots using the standards implemented.  
3. Providers are confused about the differences between Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.  

**Recommendations**
1. We recommend EP and EH/CAH be in active engagement with a public health agency for two measures from Syndromic Surveillance, Case Reporting, and/or Public Health Registry Reporting. This can be achieved from any combination of measures such as two Public Health Registry Reporting measures or one Syndromic Surveillance measure and one Case Reporting measure. |
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| **Public Health and Clinical Data Registry Reporting**  
**Measure 4:** Public Health Registry Reporting  
(Measure can count towards objective 3 times from EP and 4 times for EH/CAH) The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries. (pg. 145) | 2. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information systems, support onboarding process, and provide staff training.  
3. We recommend CMS, CDC, ONC, and other entities support pilots, using standards, to advance the maturity of the standards and address the workflow and implementation issues for Case Reporting. |
| **Public Health and Clinical Data Registry Reporting**  
**Measure 5:** Clinical Data Registry Reporting (Measure can count towards objective 3 times from EP and 4 times for EH/CAH). The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry. (pg. 147) | **Comments**  
1. There are numerous workflow and implementation issues to address for Public Health Registry Reporting.  
2. Providers are confused about the differences between Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.  
3. There needs to be clarity around the state role or responsibilities if the reporting goes straight to the CDC.  
4. It is necessary that all public health reporting be coordinated with the Public Health Agency.  
5. We recommend EP and EH/CAH be in active engagement with a public health agency for two measures from Syndromic Surveillance, Case Reporting, and/or Public Health Registry Reporting. This can be achieved from any combination of measures such as two Public Health Registry Reporting measures or one Syndromic Surveillance measure and one Case Reporting measure.  
6. We recommend removing the option of reporting directly to the CDC. It is necessary that all public health reporting be coordinated with the Public Health Agency.  
7. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information systems, support onboarding process, and provide staff training. |
| **Public Health and Clinical Data Registry Reporting** | **Recommendations**  
1. Providers are confused about the differences between Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.  
2. Clinical Data Registry Reporting including definition and process needs to be better defined and standards developed.  
3. The responsibility of the Public Health Agency to monitor and its role in the process is not clear.  
5. We recommend EP or EH/CAH whose scope of work is outside the Public Health Registry Reporting measures or if the public health agency is not capable of receiving the Public Health Registry Reporting measures, submit to at least one Clinical Data Registry Reporting measure.  
2. We recommend adding language describing the role and
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<tr>
<td>Proposed Program and Implementation Details</td>
<td>responsibility of the Public Health Agency.</td>
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<td>Comments and Recommendations</td>
<td>3. We recommend CMS, CDC, ONC and other entities provide support for development and best practices for Clinical Data Registry Reporting and the role of the Public Health Agency.</td>
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<td>4. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information systems, support onboarding process, and provide staff training.</td>
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<td>Public Health and Clinical Data Registry Reporting</td>
<td>Measure 6: Electronic Reportable Laboratory Results (Not an option for EP and Measure can count only 1 time for EH/CAH). The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. (pg. 149)</td>
</tr>
<tr>
<td>Comments</td>
<td>1. The measures of Objective 8 need to build off Meaningful Use Stage 2. Therefore, Immunization Registry Reporting and Electronic Reportable Laboratory Results should continue to be required.</td>
</tr>
<tr>
<td>Recommendations</td>
<td>1. We recommend the Electronic Reportable Laboratory Results measure be required for all EH/CAH with the proposed exclusions.</td>
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<td>2. We recommend CMS, CDC, ONC, and other federal and national entities provide technical assistance and funds to Public Health Agencies to update public health information systems, support onboarding process, and provide staff training.</td>
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<td>Public Health and Clinical Data Registry Reporting Standards</td>
<td>We support ONC’s intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we propose to define it under § 495.4 in this proposed rule and use the standards included in the 2015 Edition proposed rule published elsewhere in this edition of the Federal Register. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rules published by ONC. (pg. 150)</td>
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<td>Recommendation</td>
<td>We recommend the proposed standards in the 2015 edition base EHR for Objective 8 should be expanded to include additional public health reporting HL7 standards. Inclusion of the standards already developed and being implemented will accelerate the goal objective 8 is set forth to accomplish. The following standards support Case Reporting and Public Health Registry measures.</td>
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<tr>
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<td>1. HL7 CDA Implementation Guide for Ambulatory Healthcare Provider Reporting to Birth Defect Registries</td>
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<td>2. HL7 Version 2.6 Implementation Guide for the Messaging of Early Hearing Detection and Intervention (EHDI), Release 1 DSTU</td>
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<td>3. HL7 Version 2.6 Implementation Guide for the Messaging of Newborn Screening using pulse oximetry devices for Critical Congenital Heart Defects (CCHD), Release 1 DSTU</td>
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<td>4. V3 CDA IG: Reporting Birth and Fetal Death Info from the EHR to Vital Records, R1 (US Realm)</td>
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<td>7. Other emerging standards such as FHIR and other standards necessary for improved population and public health outcomes.</td>
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| **Clinical Quality Measure Reporting Period and Timelines.** CMS is proposing to require the same length for the CQM reporting period for EPs, eligible hospitals, and CAHs beginning in 2017 as the EHR reporting period of 1 full calendar year (pg. 163) | **Comments**  
1. There is concern about setting a specific date for required electronic eCQM submission. Additional work is necessary to improve the feasible, reliable, and accurate use of EHRs for eCQM reporting.  
2. We are concerned that CMS is proposing to adopt a specific date for electronic submission of eCQMs while proposing in a separate rule additional changes to eCQM reporting.  
3. There is concern with the required electronic reporting of CQMs in 2018, especially given the continued challenges hospitals face implementing CQMs for meaningful use. |

| EHR Technology Certification Requirements for Reporting of CQM (pg. 171)  
We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eCQMs that represent their patient populations, we would like to see EP vendors certify to all eCQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eCQMs in the selection list for those stakeholders. (pg. 171) | **Comments**  
1. There is a possibility that a CEHRT may not have CQMs applicable to a rural setting. Steps need to be taken to address rural and specialty providers’ CQM needs.  

**Recommendations**  
1. We recommend ONC and CMS work to assure that there are CQMs within the scope of practice for all meaningful use EP and EH/CAH. |

| Demonstration of Meaningful Use (pg. 174)  
We are proposing to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs. (pg. 174) | **Recommendation**  
1. We recommend ONC and CMS work towards automatic drops for attestation. Thus eliminating the manual entry into the website for attestation. |

| Exception of the Application of the Payment Adjustment to EPs in CY 2017 and subsequent years (pg. 187)  
Continue the exceptions from Stage 2: Various types of hardship exceptions that EPs could apply for, which included insufficient internet access, newly practicing EPs, extreme circumstances outside of an EP’s control, lack of control over the availability of CEHRT for EPs practicing in multiple locations, lack of face-to-face patient interactions and lack of need for follow-up care, and certain primary specialties. (pg. 188) | **Recommendation**  
1. We recommend that the full reporting period begin the January after a new EP or EH/CAH begins. Paul please verify. |

| Hospitals Eligible Under both Medicaid and Medicare (pg. 195)  
If a hospital eligible under both programs is demonstrating meaningful use for the first time, and using a continuous 90-day EHR reporting period under the Medicaid program, it could attest for the Medicaid program only, and still avoid the Medicare payment adjustment that is 2 years after the calendar year in which the EHR reporting period occurs. However, if a hospital eligible under both programs chooses also to attest for the Medicare program, it would be required to | **Recommendations**  
1. We recommend CMS provide education and outreach to assure understanding of the 90 days attestation for Medicaid. |
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<td>complete an EHR reporting period of 1 full calendar year to avoid the Medicare payment adjustment that is 2 years after that calendar year.</td>
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### State Reporting on Program Activities (pg. 207)

**Comments**

1. For the annual reporting component, Minnesota Department of Human Services already reports practice location. Currently it does not benefit Minnesota to have practice location available.
2. For quarterly reporting, Minnesota Department of Human Services does not have an issue with the 30-day turnaround.
3. Minnesota Department of Human Services does not have any concerns with State Reporting on Meaningful EHR Users.
4. The Minnesota Department of Human Services (DHS) will review the decision to manually enter CQMs in Minnesota EHR Incentive Program (MEIP). DHS will determine whether the MEIP should set policy to require providers to electronically submit eCQMs into the MEIP, mandate that providers submit to the Minnesota Department of Health with other state Medicaid quality measures, or continue the current process.

**Recommendation**

1. We support the changes to the state reporting on program activities.
2. We recommend a policy that all public health measures collected or tracked through the state reporting activities be reported to the Public Health Agency.
Appendix A: Minnesota e-Health Advisory Committee Members, 2014-15

Alan Abramson, PhD
Advisory Committee Co-Chair
Senior Vice President, IS&T and CIO
HealthPartners
Representing: Health System CIOs

Ruth Knapp
Manager, Health Data Quality
Minnesota Department of Human Services
Representing: Minnesota Department of Human Services

Daniel Abdul
Chief Information Officer
UCare
Representing: Health Plans

Marty LaVenture, PhD, MPH, FACMI
Director, Office of Health IT and e-Health
Minnesota Department of Health
Representing: Minnesota Department of Health

Wendy Bauman, MPH
Deputy Director
Dakota County Public Health
Representing: Local Public Health Departments

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

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

Bobbie McAdam
Advisory Committee Co-Chair
Senior Director, Business Integration
Medica
Representing: Health Plans

Lynn Choromanski, PhD, RN-BC
Nursing Informatics Specialist
Gillette Children’s
Representing: Experts in Health IT

Charlie Montreuil
VP, Enterprise Rewards & Corporate Human Resources
Best Buy Co., Inc.
Representing: Health Care Purchasers

Susan Heichert
Senior Vice President, Chief Information Officer
Allina Health
Representing: Large Hospitals

Kevin Peterson, MD
Family Physician
Phalen Village Clinic
Representing: Community Clinics and FQHCs

Maureen Ideker, MBA, RN
Director of Telehealth
Essentia Health
Representing: Small and Critical Access Hospitals

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

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

Peter Schuna
Director of Strategic Initiatives
Pathway Health Services
Representing: Long Term Care

Paul Kleeberg, MD
Clinical Director
Regional Extension Assistance Center for HIT
Representing: Physicians

Cheryl M. Stephens, MBA, PhD
Executive Director
Community Health Information Collaborative
Representing: Health IT Vendors
Donna Watz, JD  
Deputy General Counsel  
Minnesota Department of Commerce  
Representing: MN Department of Commerce

Marty Witrak, PhD, RN  
Professor, Dean  
School of Nursing, College of St. Scholastica  
Representing: Academics and Research

Cally Vinz, RN  
Vice President, Health Care Improvement  
Institute for Clinical Systems Improvement  
Representing: Clinical Guideline Development

Bonnie Westra, PhD, RN, FAAN, FACMI  
Associate Professor  
University of Minnesota, School of Nursing  
Representing: Nurses

Ken Zaiken  
Consumer Advocate  
Representing: Consumers

Kathy Zweig  
Associate Publisher & Editor-in-Chief  
Inside Dental Assisting Magazine  
Representing: Clinic Managers

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

Jeff Benning, MBA  
President and CEO  
Lab Interoperability Collaborative  
Alternate Representing: Expert in HIT

Barb Daiker, RN, PhD  
Manager of Quality Improvement  
Minnesota Medical Association  
Alternate Representing: Physicians

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St. Paul-Ramsey Department of Public Health  
Alternate Representing: Local Public Health

Nancy Garrett, PhD  
Chief Analytics Officer  
Hennepin County Medical Center  
Alternate Representing: Large Hospitals

Susan Severson  
Director, Health IT Services  
Stratis Health  
Alternate Representing: Quality Improvement

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

Trisha Stark, PhD, LP, MPA  
Licensed Psychologist  
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Meyrick Vaz  
Vice President - Healthcare Solutions  
Optum Global Solutions  
Alternate Representing Vendors