Overview of Specialized Registries

James Daniel
April 26, 2016
Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 and 2017

• Align all three stages of Meaningful Use into single program/rule
  – All providers would meet Stage 3 requirements starting in 2018
  – Phased-in timelines that allows some providers to continue to meet Stage1 and Stage 2 requirements in 2017

• Aligns reporting periods – calendar year reporting for eligible professionals, eligible hospitals and critical access hospitals
  – Full year reporting periods
  – Allows 90 day reporting periods for first time attesters in 2017 only

• Provides simplified objectives and measures –
  – Modification: Objective 10: Public Health and Clinical Data Registry Reporting
  – Stage 3: Objective 8: Public Health and Clinical Data Registry Reporting

• New 2015 Base EHR Definition
• No optional/required criteria – developers should choose the criteria relevant to their purpose
• Can be used beyond CMS EHR Incentive Program
# Mod Rule: Measures for Objective 10

<table>
<thead>
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<td>Measure 3 – Case Reporting (Dropped)</td>
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<td>Measure 4 - Public Health Registry Reporting</td>
<td>2</td>
<td>3</td>
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<tr>
<td>Measure 5 - Clinical Data Registry Reporting (Now Specialized Registries Includes Cancer for EP)</td>
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<td>Measure 6 - Electronic Reportable Laboratory Results</td>
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## Stage 3: Measures for Objective 8

### PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

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• Active engagement means that the provider is in the process of moving towards sending "production data" to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry.

• We noted that the term "production data" refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers.

• We proposed that "active engagement" may be demonstrated by any of the following options:
  – Option 1 – Completed Registration to Submit Data:
  – Option 2 - Testing and Validation
  – Option 3 – Production
We thank the commenters for their input and note the following clarifications of intent and purpose for the change from “ongoing submission” to “active engagement.” We received feedback from a variety of stakeholders that the "ongoing submission" structure created confusion. This feedback highlighted that providers are unsure of how ongoing submission could be achieved and whether periodic, continuous, or episodic reporting was generally required. We found that the wide variation among potential provider reporting scenarios and submission processes contributed to the difficulty in defining “ongoing submission” in a fair and universally applicable manner. Therefore our change to “active engagement” is intended to more clearly identify the progression of the requirement as well as providing a basis for defining the actions required by the provider in each step of the process. In a sense, the active engagement options are a clarification of the more basic concept of reporting which is that the provider is taking action and in communication with a public health agency in order to register, test and submit data in a progression which results in the provider successfully reporting relevant data to the public health agency.

The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and renames the requirement to better describe the provider’s role in meeting each option within the structure. There is an intentional similarity between some of the broad descriptions of the Stage 2 “ongoing reporting” and the requirements for the “active engagement” options. This is both to provide continuity and to define a more comprehensive progression for providers in meeting the measure. For example, in the Stage 2 rule (77 FR 54021), we generally stated that a provider could register their intent to submit data to successfully meet a measure in the public health objective. This concept is defined with additional guidance in the Stage 3 proposed rule as Active Engagement Option 1: Completed Registration to Submit Data.

For the commenters discussing the submission of production data as defined in Action Engagement Option 3: Production, we note that under this option a provider only may successfully attest to meaningful use when the receiving public health agency or clinical data registry moves the provider into a production phase. We recognize that live data may be sent during the Testing and Validation phase of Option 2, but the data received in Option 2 is not sufficient for purposes of meeting Option 3 unless the public health agency and clinical data registry is actively accepting the production data from the provider for purpose of reporting. We agree with commenters who noted that issues may arise that require provider action. In such a case, we require providers to respond to issues in the same manner as described in Option 2. For example, a provider in the production phase would not be able to successfully attest to Option 3 if there were issues in production where the provider fails to respond to an issue within 30 days on two occasions.
As we have noted in the proposed rule, under the active engagement requirement, **providers would only need to register once** with a public health agency or a clinical data registry and could register before the reporting period begins. In addition, we note that **previous registrations with a public health agency or clinical data registry that occurred in a previous stage of meaningful use could count toward option 1** of the active engagement requirement for purposes of attesting to Stage 3. We clarify that providers **must register with a public health agency or clinical data registry for each measure** they intend to use to meet meaningful use. Further, we also clarify that to meet option 1 of the active engagement requirement, registration with the applicable public health agency or clinical data registry is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.
Active Engagement (page 430-31)

The EHR Incentive Programs are based on individual providers meeting the objectives and measures of meaningful use. Therefore an individual provider can only meet an objective or measure if they are engaged in the activity which is used to meet the measure. This means a provider can demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the provider directly for individual reporting. Or, a provider also may demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the practice or organization of the provider if the organization reports at the group level as long as the provider is contributing to the data reported by the group. If the provider does not contribute to the data, they must claim the exclusion if applicable and/or meet another public health reporting measure. For example, a provider who does not administer immunizations should claim the exclusion even if their organization submits immunization reporting at the group level.
In response to comments received and the concern that providers need advance readiness notification from public health agencies and clinical data registries to prepare and plan before the EHR reporting period begins, we are broadening the exclusions that could apply to providers seeking to meet the objective. The exclusion will allow providers more time to prepare their processes to align with what data public health jurisdictions are ready to accept. Specifically, we will not finalize the proposed requirement that public health agency and clinical data registries declare readiness on the first day of the EHR reporting period. We are instead finalizing a modified exclusion that if public health agencies have not declared 6 months before the start of the EHR reporting period whether the registry they are offering will be ready on January 1 of the upcoming year for use by providers seeking to meet EHR reporting periods in that upcoming year, a provider can claim an exclusion. We believe that modifying the exclusion to request public health agency or clinical data registry to declare their readiness 6 months ahead of the first day of the EHR reporting period would allow providers adequate notice of public health agency and clinical data registry plans to accept data at the beginning of an EHR reporting period.
**Declaration of Readiness**

Public health agency (PHA) publicizes its readiness to accept electronic data per any specified MU standards for each of its registries and informs CMS if applicable.

**Registration of Intent**

Eligible professionals (EPs) and eligible hospitals (EHs) notify PHA in writing what public health objectives they seek to meet.

**On-Boarding**

EPs and EHs work with PHAs to establish on-going MU data submission.

**Acknowledgment of On-going Submission**

PHAs affirm that EPs and EHs have successfully submitted with written affirmation, which may be electronic and/or automatically generated.

Who: PHA to post publicity to local partners, and to CMS if applicable

When: At the point of readiness

Who: EPs and EHs to PHAs

When: Before 50th day of reporting period

Who: EPs and EHs to PHAs

When: Following registration and in response to PHA requests for action

Who: PHA to EPs and EHs

When: Upon successful submission of public health MU data to PHA
What does this mean for PH/Specialized Registry

- In Modified Stage 2 and MU3 PHAs are tasked with declaring their readiness to accept data from Providers, registering Providers that intend to submit data, establishing a testing and validation process to onboard Providers, and acknowledging those Providers that successfully submit data. **It is not the role of the PHA to determine if Providers meet MU measures or qualify for incentive payments.**

- Outcomes from Providers registering their intent to meet MU public health measures should include:
  - PHAs having information on Providers planning to submit data to the PHA for Modified Stage 2 and MU3.
  - Providers having the information they need to begin on-boarding.

- To successfully achieve these outcomes, PHAs should develop processes and tools to facilitate registering, on-boarding, and acknowledging Providers. A critical success factor will be tracking and documenting communications between a PHA and Providers reporting within their jurisdiction. The PHA registration process should provide some type of confirmation (e.g., email, webpage confirmation, letter) when the Provider successfully registers. The Providers will need this documentation to support their attestation for Modified Stage 2 and MU3.
What is On-Boarding?

- On-boarding refers to the testing and validation process in which Providers and PHAs collaboratively engage to integrate clinical electronic data feeds into public health surveillance systems and registries. Providers participate in a PHA’s on-boarding process by first registering with a PHA (see Registration of Intent section for additional details) and then responding to a PHA’s written request for action. These actions can include sending data to a PHA for validation and correcting data in response to a PHA’s validation feedback.

- Since there are multiple Modified Stage 2 and MU3 public health measures, Providers may be concurrently engaged with a PHA in multiple on-boarding processes. An on-boarding process ends when the Provider is routinely submitting production data that passes PHA’s validation. Production data refers to data generated through clinical processes involving patient care, and it is used to distinguish between this data and test data which may be submitted for the purposes of enrolling in and testing electronic data transfers.
Key Process Communications:

• Providers intending to initiate ongoing submission for Modified Stage 2 and MU3 measures register their intent to submit data to the PHA.

• PHA registration process provides confirmation when the Provider successfully registers their intent.

• PHA should be able to provide appropriate documentation for Providers regarding their current Active Engagement status.
  – When PH(Specialized Registry) requested action
  – When Provider responded to request
• PHAs will need to track the status of Providers throughout the on-boarding processes.
  – waiting for on-boarding invitation,
  – invited to on-board
  – currently on-boarding
  – in production
• The tracking of the on-boarding process by a PHA should, at minimum, record when written requests to take action are sent to the Provider and when a Provider responds to these written requests.
• These written requests should include invitations to begin on-boarding and requests for corrective actions the Provider may need to take during testing and validation. A Provider’s engagement in the testing and validation process can be demonstrated by the Provider’s responses to written requests for action from the PHA, or by any other evidence of compliance with the PHA’s request.
• Upon completion of the on-boarding process, the PHA should send or publish communication(s) for the Provider confirming the Provider was able to submit the relevant public health data (see Acknowledgements of Submission of Production Data section for additional details). A Provider that can only submit reportable data in a test environment has not achieved Active Engagement Option 3 - Production.
• The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.
• The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.
In the Stage 2 final rule, we were purposefully general in our use of the term “specialized registry” (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and responses to the February 2014 Public Health Reporting RFI; we propose to carry forward the concept behind this broad category from Stage 2, but also propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a “public health registry” as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023).
For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist's provision of care. Clinical data registries can also be used to monitor health care quality and resource use.
...we agree that our proposal to split the Specialized Registry Reporting objective into two measures may inadvertently cause some providers to no longer use their current reporting option to meet the measure. We are therefore not finalizing our proposal to split specialized registry reporting into two measures as proposed. Instead, we will maintain for 2015 through 2017 a unified specialized registry reporting measure which adopts the change from "ongoing submission" to "active engagement". We believe that this will allow providers flexibility to continue in the direction they may have already planned for reporting while still allowing for a wide range of reporting options in the future.
As noted previously, we are not adopting this policy for the public health reporting measure, and we are also therefore not adopting the policy for a separate clinical data registry reporting measure.
We further note that we have previously supported the inclusion of a variety of registries under the specialized registry measure, including Prescription Drug Monitoring Program reporting and electronic case reporting. We agree that a variety of registries may be considered specialized registries, which allows providers the flexibility to report using a registry that is most helpful to their patients. **Therefore, we will continue to allow these registries to be considered specialized registries for purposes of reporting the EHR Reporting period in 2015, 2016, and 2017.** However, **we will modify the exclusion not only to reflect the change from public health registry to specialized registry but also to allow an exclusion if the provider does not collect the data relevant to a specialized registry within their jurisdiction.**
We are also finalizing our proposed policy to incorporate cancer case reporting into the measure for EPs only. Therefore, EPs who were previously planning to attest to the cancer case reporting objective, may count that action toward the Specialized Registry Reporting measure.
...public health jurisdictions began to accept electronic case reporting and prescription drug monitoring during previous stages of meaningful use and these reporting options were considered specialized registries.

...we will allow such specialized registries to be counted for purposes of reporting to this objective in Stage 3 under the public health registry reporting measure for Stage 3 in 2017, 2018 and subsequent years in the following manner: A provider may count a specialized registry if the provider achieved the phase of active engagement defined under Active Engagement Option 3: Production, including production data submission with the specialized registry in a prior year under the applicable requirements of the EHR Incentive Programs in 2015 through 2017. We do note that reporting to specialized registries does not require certification under the ONC Health IT Certification Program or adherence to specific implementation guides for reporting in 2015 through 2017, and we direct readers to section aII.B.2.b.x for further information on the Specialized Registry Reporting measure for 2015 through 2017.
Stage 3: Measure 5 Clinical Data Registry

Our definition of jurisdiction here is general, and the scope may be local, state, regional or at the national level. The definition will be dependent on the type of registry to which the provider is reporting. A registry that is "borderless" would be considered a registry at the national level and would be included for purposes of this measure.
Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.
Exclusions for Measure 5 Clinical Data Registry Reporting

Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.
We believe that the measure and associated exclusions that we have proposed provide a variety of options for providers to successfully attest or as appropriate be excluded from the measure.

(Mod rule changes noted to reflect Specialized Registries)
However we note that providers would not be able to count production reporting to a specialized registry under the Public Health Reporting Objective for 2015 through 2017, if there are standards and requirements referenced in the ONC 2015 Edition regulations for Public Health and Clinical Data Registry Stage 3 Measures.
WA DOH Meaningful Use: PDMP as a Specialized Registry
Maximizing Resources

WA’s journey to offering PMP for MU wasn’t linear and didn’t emanate from a single motivation, but was the result of considering how to make the most/best use of each of the resources in play.
The PMP Solution- “An Overview”

WA’s PMP is a program designed to improve patient safety and protect public health with the goal of reducing overdose deaths, hospitalizations, and other related prescription drug abuse issues.

1. Records for dispensing of controlled substances are submitted to a central database by pharmacies and other dispensers.

2. Health providers and other authorized users are able to register for access, and once approved, can view information through a secure web portal.

3. PMP information helps providers avoid duplicative prescribing and dangerous drug interactions; and helps to identify substance abuse or pain management issues.
Unintentional Prescription Opioid Overdose Deaths
Washington 1995-2014

Source: Washington State Department of Health, Death Certificates

[Graph showing the number of deaths from 1995 to 2014, with a significant increase in the latter years.

The graph indicates a steady increase in deaths from prescription opioids, with a sharp rise in 2014, reaching 319 deaths.

Legend:
- Yellow: Prescription Opioid + alcohol or illicit drug
- Blue: Prescription Opioid +/- Other Prescriptions

PMP Jan 2012]
Low rate of PMP use. To adequately address the Rx epidemic we need more use of the system. Ideally 1:1 PMP query to CS Rx.

- Only 33% of WA CS prescribers registered for PMP
  - Voluntary usage of PMP, No statewide mandate for registration or use
  - WA delegate access requires prescribers to register for PMP and manage their delegates on the system.
  - Registration ... ya’ got a minute?

*The key issue found when surveying prescribers why they don’t use the PMP:* Ease of access!

...or not so much
Instant Information
Well, Kinda...

In the healthcare provider’s office the clock is ticking.

• Predetermined Workflow
• Difficult to Accurately Determine Risk Potential

Accessing and querying the PMP takes minutes, not lots of minutes, but minutes just the same. Registration takes longer.
Evolution

✓ CS Rx info available to providers on the PMP
✓ PMP info effective when utilized
🚫 PMP not being used by providers with enough frequency due to accessibility

How do we make CS Rx info available to providers more effectively? – Can it be pushed?
• Secure connection with certified EHR may provide a means.
Emergency Department Information Exchange

An Unintended Test Case
PMP-EDIE Integration

2013 Legislation (PMP funding) required DOH to integrate PMP with Washington’s Emergency Department Information Exchange (EDIE)

• Legislation gave a small budget proviso, but no ongoing funds for this connection meant that the PMP wouldn’t have the resources to upkeep a 1:1 connection.

How do we keep this operating sustainably?
PMP – HIE – EDIE

WA Health Information Exchange

• Eyes on future benefits:
  – Leveraging the HIE allows an ongoing connection with EDIE with no additional cost to program.
  – By building our connection between the PMP and the HIE, future HIE trading partners could take advantage of PMP data with no additional program work or cost.
Brief Overview of the WA HIE

2009 American Recovery and Reinvestment Act

- Washington State HITech grant dollars were used to fund a statewide Health Information Exchange (HIE).
  - OneHealthPort managed the vendor selection process and designed the HIE model based on community/constituent input
  - OHP HIE is an “exchange” model – no central repository
  - OHP HIE can leverage many large existing repositories (EPIC, other EHRs, state agency systems, etc.)
  - OHP HIE provides secure, trusted trading options
    - Hosted central web services
    - Central meeting point for secure connections
    - Leveraging and promoting data standards
Leveraging WA’s HIE for the PMP – EDIE Connection
Quote from End User (benefits of automated HIE query)

• "Just as creating a PMP was a game changer in it's relationship to coordinating the care of our most at risk patients in WA State, pushing that information without provider bias, without burdensome hurdles, now pretty much mandates providers be aware of these patient's special needs and risks. It's the next level that all of the nation can learn from."
EDIE Current Status

• As of July 2016:
  – 78 hospitals (EDs) are live with EDIE-PMP connection
  – In 2015 over 2.2 million EDIE queries were submitted via HIE to the PMP
    • For 2015 that’s 1.5 X’s as many as from our online portal - from all health care providers in all other health care settings.

Query Automation = Exponential Query Growth
PMP for MU - Incentivization

- WA PMP active since Jan 2012
- Active HIE
  - PMP–HIE live connection
- EDIE connection
  - Proof of concept for EHR connection
  - Validation of automation

What do we have to do to get organizations to take advantage of this?

Incentivize
PMP & Meaningful Use

Stage 2 & 3 Meaningful Use Approval: WA DOH has approved the PMP as an official “other specialized registry” in compliance with stage 2 & 3 meaningful use

• Listed as an EP & EH Public Health Measure-Specialized Registry

• For MU Registration we accept group registrations (a health system can register multiple sites at once)

• Professionals need to have an active account with the PMP in order for requests to process

• Onboard with OHP using the NCPDP 10.6 transactions (typically part of the medication reconciliation module already)
MU Current Status

As of July 2016:

- 84 WA health systems (over 1,000 locations) have registered intent to use PMP for MU

- 3 health systems have begun the process for testing EHR-HIE-PMP connection

- CMS has recognized PMP for MU now and moving forward
S&I Epic Pilot
PMP Pilot with Epic

- Standard & Interoperability Framework – sponsored by the Office of the National Coordinator (DHHS)
- WA chosen as a pilot site
- Began work with Epic in April 2015
- Completed pilot in October 2015
- Epic has released the update and it is available to WA customers
Epic Use Case (From S&I)

Pre-Step: Healthcare Professional logs into Health IT System

1. Sends query to state PDMP

Healthcare Professional receives requested information

2. PDMP sends query response

PDMP & HIT Integration Use Case Scope

- EHR system and HIE connection are trusted partners. PMP is able to transact data directly bypassing the cumbersome Single Sign On Portal.

- Using the EHR system allows access to PMP data from the normal workflow – No or minimal added time and effort

- EHR system is able to ingest and retain PMP data for future use
Challenges/Lessons Learned

- PMP legislation was not forward thinking enough (no HIE, authorizing facilities, etc...). Audit trails (tracking requests by facility or end user).
  - Requests were required to be tracked to the individual user
  - EDIE and ADT request
  - HB 2730
- Patient Matching (no pick list)
- Different data transmission standards (use of different standards, translation could leave data unencrypted)
- Avoiding too many data sharing agreements
- If you build it, “they” may not necessarily come (MU)
  - Many facilities have competing priorities with MU and ICD-10
  - The providers love the idea but have to sell it to their administration
- WA’s PMP is housed at DOH. State’s whose PMP’s are housed with BOP or LE agencies still have this eligible, and WA’s ground work already laid.
HB 2730

BEFORE

• Only CS Prescribers
• No Delegates for RPH
• All transactions under individual provider
  PMP acct #/license #

AFTER

• All Prescribers
• RPH Delegate Authority
• Licensed HC facilities authorized to transact
  PMP data using EHR-HIE connection
Prescription Review

- **Contact Info:**
  - Gary Garrety, Operations Manager
  - Phone: 360.236.4806
  - Email: prescriptionmonitoring@doh.wa.gov
  - Website: [http://www.doh.wa.gov/pmp](http://www.doh.wa.gov/pmp)
Expanded Support for Medicaid Health Information Exchanges

Thomas Novak
Medicaid Interoperability Lead

Office of Policy
Office of the National Coordinator for Health IT
Medicaid Data & Systems Group
Centers for Medicare and Medicaid Services
Agenda

- Background
- State Medicaid Director’s Letter 16-003 of 2/29/2016
- How it works
- Possible Activities
  - Support for HIE Architecture
  - Support for HIE On-Boarding
- HIE Architecture Specifics
- Interoperability Standards
- CMS Oversight
- Questions?
Background

- Since 2012, $350 million has been approved by CMS for Medicaid HITECH support for HIEs supporting EPs and EHs under current guidance
- Potential $45 million increase from 2015 to 2016, though not a yearly increase that is necessarily sustainable till 2021.
Background

- The guidance of how to allocate the matching funds for interoperability and Health Information Exchange (HIE) activities was based on the State Medicaid Director’s letter of May 18, 2011*
- Matching funds were limited to supporting HIE for Eligible Professional and Eligible Hospitals, that is, Eligible Providers (EPs) who were eligible for EHR incentive payments – a smaller subset of Medicaid providers that excluded post-acute care, substance abuse treatment providers, home health, behavioral health, etc.
- That guidance was issued when Meaningful Use Stage 1 was in effect. Meaningful Use Stage 2 and Stage 3, however, later broadened the requirements for the electronic exchange of health information

Bridging the Healthcare Digital Divide: Improving Connectivity Among Medicaid Providers

Connecting All Parts of the Health System

That’s why today, we are announcing an initiative to bring interoperable technology to a broader universe of health care providers, including long-term care, behavioral health providers, substance abuse treatment centers, and other providers that have been slower to adopt technology. This announcement will help to bridge an information sharing gap in Medicaid by permitting states to request the 90 percent enhanced matching funds from CMS to connect a broader variety of Medicaid providers to a health information exchange than those providers who are eligible for such connections today. This additional funding will enhance the sustainability of health information exchanges and lead to increased connectivity among Medicaid providers.

Doctors and other clinicians need access to the right information at the right time in a manner they can use to make decisions that impact their patient’s health. The free flow of information is hampered when not all doctors, facilities or other practice areas are able to make a complete circuit. Adding long-term care providers, behavioral health providers, and substance abuse treatment providers, for example, to statewide health information exchange systems will enable seamless sharing of a patients’ health information between doctors or other clinicians when it’s needed. This sharing helps create a more complete care team to collaborate on the best treatment plans and goals for Medicaid patients.

Andy Slavitt, Centers for Medicare & Medicaid Services (CMS) Acting Administrator,
Karen DeSalvo, National Coordinator for Health Information Technology (ONC) and Acting Assistant Secretary for Health

The CMS Medicaid Data and Systems Group and ONC Office of Policy have partnered to update the guidance on how states may support health information exchange and interoperable systems to best support Medicaid providers in attesting to Meaningful Use Stages 2 and 3:

- This updated guidance will allow Medicaid HITECH funds to support all Medicaid providers that Eligible Providers want to coordinate care with.
- Medicaid HITECH funds can now support HIE onboarding and systems for behavioral health providers, long term care providers, substance abuse treatment providers, home health providers, correctional health providers, social workers, and so on.
- It may also support the HIE on-boarding of laboratory, pharmacy or public health providers.

State Medicaid Directors Letter

The basis for this update, per the HITECH statute, the 90/10 Federal State matching funding for State Medicaid Agencies may be used for:

“pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.”*

How it works:

- This funding goes directly to the state Medicaid agency in the same way existing Medicaid HITECH administrative funds are distributed.
  - State completes IAPD (Implementation Advanced Planning Document) to be reviewed by CMS.
  - States complete Appendix D (HIE information) for IAPD as appropriate.
- This funding is in place until 2021 and is a 90/10 Federal State match. The state is still responsible for providing the 10%.
- The funding is for HIE and interoperability only, not to provide EHRs.
- The funding is for implementation only, it is not for operational costs.
- The funding still must be cost allocated if other entities than the state Medicaid agency benefit.
- **All providers or systems supported by this funding must connect to Medicaid EPs.**
Possible Activities
HIE On-Boarding

State Medicaid Agencies may use this enhanced funding to on-board Medicaid providers who are not incentive-eligible, including public health providers, pharmacies and laboratories.

**On-boarding**: the technical and administrative process by which a provider joins an HIE or interoperable system and secure communications are established and all appropriate Business Associate Agreements, contracts and consents are put in place. State activities related to on-boarding might include the HIE’s activities involved in connecting a provider to the HIE so that the provider is able to successfully exchange data and use the HIE’s services. The 90 percent HITECH match is available to cover a state’s reasonable costs (e.g., interfaces and testing) to on-board providers to an HIE.

So, for example:

- Long term care providers may be on-boarded to a statewide provider directory
- Rehabilitation providers may be on-boarded to encounter alerting systems
- Pharmacies may be on-boarded to drug reconciliation systems
- Public health providers may be on-boarded to query exchanges
- EMS providers may be on-boarded to encounter alerting systems
- Medicaid social workers may be connected to care plan

Such on-boarding must connect the new Medicaid provider to an EP, and help that EP in meeting MU
HIE Architecture Specifics
Provider Directories

- **Definition** – A system that supports management of healthcare provider information, both individual and organizational (Source: IHE).
  - Information about the provider: Can include demographics, physical addresses, credential and specialty information, and electronic endpoints to facilitate trusted communications with a provider.
  - Information about the provider’s relationships:
    - Affiliation with other organizations and providers.
    - Health Information Exchange (HIE) and members
    - Integrated Delivery Networks and care delivery members.
    - Hospitals, their practitioners, and their sub-organizations.
Provider Directories

• MMIS funding has always been available for Medicaid provider directories but MMIS funding limited states to supporting in-house provider directories. This new option allows for the inclusion of all Medicaid providers in statewide HIE’s provider directory, so long as such connections help Eligible Providers with Meaningful Use.

• **Scenario 1: Health Information Exchange.**
  • A provider is preparing to transition their patient to a long-term care facility and uses a provider directory to look up the electronic endpoint (e.g., Direct Address or query endpoint) for where to send the summary of care record.

• **Scenario 2: Electronic Prescribing.**
  • A hospital is about to generate and transmit a discharge prescription electronically, and it uses a provider directory to look up the pharmacy to which it will send the prescription.
Secure Messaging

- Definition: ability to send and receive secure information electronically between care providers to support coordinate care. May also be used between patients and their providers. Sometimes called “point-to-point” exchange or “push” exchange.

- Secure messaging may support the following MU measures:
  - Transitions of Care
  - View, Download or Transmit

- Direct: National standard for secure messaging
  - Role in CEHRT – Products are certified using Direct; required for Stage 2 but providers do not need to use Direct for Stage 3 MU
  - DirectTrust – A trust community that enables providers in one HISp to communicate with providers from another HISp without one-off data sharing agreements
Encounter Alerting

- Encounter alerting provides real-time electronic notification when patients are admitted to, discharged from, or transferred from a hospital using Admission, Discharge, and Transfer (ADT) messages.
- Encounter alerting notifies primary care providers and care coordinators about health care encounters (e.g., ED visits, hospital admissions) and assists with follow up care coordination.

- **Potential Meaningful Use Objectives** - Health Information Exchange Objective Measure 1
Care Plan Exchange

- Sending an electronic care plan between providers (physical and behavioral health, for example)
- MU alignment:
  - Summary of Care
  - Health Information Exchange
  - View, download, transmit
Care Plan Exchange

• A Care Plan (including Home Health Plan of Care (HHPoC)) is a consensus-driven dynamic plan that represents a patient’s and Care Team Members’ prioritized concerns, goals, and planned interventions. It serves as a blueprint shared by all Care Team Members (including the patient, their caregivers and providers), to guide the patient’s care. A Care Plan integrates multiple interventions proposed by multiple providers and disciplines for multiple conditions.

• A Care Plan represents one or more Plan(s) of Care and serves to reconcile and resolve conflicts between the various Plans of Care developed for a specific patient by different providers. The Care Plan also serves to enable longitudinal coordination of care.

• 2015 Edition Certification Health IT Final Rule introduces new criterion for Care Plan 170.315 (b)(9)
  • New criterion requires a Health IT Module to enable a user to record, change, access create and receive care plan information in accordance with the HL7 C-CDA Release 2.1 Implementation Guide (Standard)
Care Plan Exchange

**Scenario 1: Unidirectional Exchange of a Care Plan** during a complete handoff of care form the sending Care Team (e.g. Hospital setting) to a receiving Care Team (e.g. Home Health Agency and PCP)

**Scenario 2: Exchanging a Care Plan between Care Team Members and a Patient**

- **Setting 1:** Hospital or ED where Patient is discharged from sends Care Plan to Care Team in non-acute care setting
- **Setting 2:** Care Team including Patient in Acute Care Setting creates harmonized Care Plan for exchange with a second Care Team in a non-acute care setting
- **Setting 3:** Patient receives Care Plan in their personal health record application or patient system.
HISP Services

Health Information Service Providers are entities that provide secure messaging services, using Direct, to providers and consumers.

• **Value**: Think of a HISP as an e-mail service provider. You need them behind the scenes to make sure your messages are being sent and received properly and securely on your behalf.

• HISP Services are offered by EHR publishers, HIEs, for profit service providers, etc.

• They are usually offered as a paid subscription or by a per transaction rate.
HISP Services

- **Health Information Service Providers (HISPs)** serves as a health data intermediary providing the secure communication across organizations and providers.
- Message senders can create a message in standardized message format and routing with secure transport protocols to the appropriate recipient.
- Message senders and recipients receive a unique email address used for HISP secure messaging and must be connected to a HISP or use technology with the same functions as a HISP.
- States may need to review the HIE governance and policies to determine if non-covered entities can be HISP users.
- **Meaningful Use Objective** – Health Information Exchange Measures 1, 2 and/or 3.

### Health Information Service Provider Examples

<table>
<thead>
<tr>
<th>Health Information Service Provider Examples</th>
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<tbody>
<tr>
<td>Regional Health Information Organization (RHIOs) services</td>
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<tr>
<td>State-level HIE</td>
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</tbody>
</table>
Query Exchange

- Query exchange – used by providers to search and discover accessible clinical data on a patient. This type of exchange is often used when delivering unplanned care.
- Can support MU “Transitions of Care” measure (by meeting other technical requirements and assuming numerators and denominators can be measured by providers)
- Requires trust relationships to be established between participants before data may be exchanged. Governance organizations, often called Health Information Organizations (HIOs), provides the trust relationships (provides policy, agreements, technical security infrastructure, etc.)
Public Health Systems

The public health systems that support Eligible Providers in achieving Meaningful Use may now be supported:

• Immunization Registries
• Syndromic Surveillance Registries
• Specialty Registries
  • Prescription Drug Monitoring Programs (non-MMIS)
  • Other diseases/conditions that are state priorities (homelessness, lead exposure, etc.)
• Architecture for the registries can now be supported, not just connections
Public Health Systems

- PDMP On-Boarding
- SMDL #16-003 can support, “costs eligible for the 90 percent HITECH match might include costs related to developing registry and system architecture for Prescription Drug Monitoring Programs (PDMPs), as per FAQ #134137 PDMPs can be considered a specialized registry to which Eligible Providers may submit data in order to meet Meaningful Use objectives. States should, however, keep in mind that MMIS matching funds might in some circumstances be a more appropriate source of federal funding for costs related to developing a PDMP”.
Interoperability Standards

• Medicaid systems must adhere to Medicaid Information Technology Architecture (MITA)*, which requires adherence to seven conditions and standards:
  - Modularity Standards
  - MITA Condition
  - Industry Standards Condition
  - Leverage Conditions
  - Business Results Condition
  - Reporting Condition
  - Interoperability Condition

Interoperability Standards

December 4, 2015, CMS Final Rule on, “Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems,” published describing “industry standards,” as aligned with ONC standards:

§433.112 FFP for design, development, installation or enhancement of mechanized processing and information retrieval systems.

* * * * *

(b) CMS will approve the E&E or claims system described in an APD if certain conditions are met. The conditions that a system must meet are:

* * * * *

(12) The agency ensures alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B: the HIPAA privacy, security and transaction standards; accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards adopted by the Secretary under section 1104 of the Affordable Care Act; and standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act.
Interoperability Standards

What’s in 45 CFR Part 170?

• Transport standards (e.g. Direct)
• Functional standards (e.g. clinical decision support)
• Content exchange standards (e.g. CCDA)
• Implementation specifications for exchanging electronic health information
• Vocabulary standards for representing electronic health information
CMS Oversight

Cost allocation requirements from SMD 11-004* remain in place:

CMS will work with States on an individual basis to determine the most appropriate cost allocation methodology.

- HITECH cost allocation formulas should be based on the direct benefit to the Medicaid EHR incentive program, taking into account State projections of eligible Medicaid provider participation in the incentive program.
- Cost allocation must account for other available Federal funding sources, the division of resources and activities across relevant payers, and the relative benefit to the State Medicaid program, among other factors.
- Cost allocations should involve the timely and ensured financial participation of all parties so that Medicaid funds are neither the sole contributor at the onset nor the primary source of funding. Other payers who stand to benefit must contribute their share from the beginning. The absence of other payers is not sufficient cause for Medicaid to be the primary payer.

### Sample Cost Allocation Plan

<table>
<thead>
<tr>
<th>Federal/State Program</th>
<th>Medicaid Share (%/$)</th>
<th>Federal Share (%/$)</th>
<th>State Share (%/$)</th>
<th>TBD Share (duplicate this column as many times as necessary) (%/$)</th>
<th>Total Program Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid EHR Incentive Program</td>
<td></td>
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</table>

CMS Oversight

- New funding must connect Medicaid providers to EPs and map to specific MU measures (to be described by the state)
- Implementation benchmarks to be defined by the state
- States should assume data will be requested regarding MU implications of new systems and newly on-boarded providers
- For new systems without defined data standards (Encounter Alerting, Care Plan Exchange), the systems must still support some MU measure to be defined by the state.
CMS Oversight

Existing guidance on other activities that can be supported remains in place:

- Personal Health Records
- System and resource costs associated with the collection and verification of meaningful use data from providers’ EHRs
- System and resource costs to develop, capture, and audit provider attestations
- Evaluation of the EHR Incentive Program (Independent Verification (IV) & Validations (V) and program’s impact on costs/quality outcomes)
- Data Analysis, Oversight/Auditing and Reporting on EHR Adoption and Meaningful Use
- Environmental Scans/Gap Analyses
- SMHP updates/reporting; IAPD updates
- Developing Data Sharing & Business Associate Agreements (legal support,
- Ongoing costs for Quality Assurance activities Multi-State Collaborative for Health IT annual dues Staff/contractual costs related to the development of State-Specific meaningful use and patient volume criteria Medicaid Staff Training/Prof. Development (consultants, registration fees, etc.)

CMS Oversight
(cont’d)

• System and resource costs associated with the National Level Repository (NLR) Interface
• System and resource costs associated with State interfaces of a Health Information Exchange (HIE)--(e.g., laboratories, immunization registries, public health databases, other HIEs, etc.)
• Creation or enhancement of a Data Warehouse/Repository (should be cost allocated)
• Development of a Master Patient Index (should be cost allocated)
• Communications/Materials Development about the EHR Incentive Program and/or EHR Adoption/meaningful use
• Provider Outreach Activities (workshops, webinars, meetings, presentations, etc).
• Provider Help-Line/Dedicated E-mail Address/Call Center (hardware, software, staffing)
• Web site for Provider Enrollment/FAQs
• Hosting Conferences/Convening Stakeholder Meetings
• Business Process Modeling
Utilize technology to gather information

- Basic EHR functionality, structured data
- Privacy & security protections
- Connect to Public Health

Improve access to information

- Care coordination
- Patient engaged
- Privacy & security protections
- Structured data utilized for Quality Improvement

Data utilized to improve delivery and outcomes

- Patient self management
- Evidenced based medicine
- Registries for disease management
- Privacy & security protections
- Connect to Public Health

Enhanced access and continuity

- Data utilized to improve delivery and outcomes
- Patient engaged, community resources
- Patient centered care coordination
- Team based care, case management
- Registries to manage patient populations
- Privacy & security protections
- Connect to Public Health

Use information to transform

Deliver System Reform
Questions

For states with questions:

• Email questions to: CMS.AllStates@briljent.com

• Contact your Regional CMS Medicaid HITECH lead for support or see www.medicaidhitechta.org

• ONC is a partner is supporting the HIEs as well thomas.novak@hhs.gov