Public Health Agency Readiness for Meaningful Use, 2015 - 2018

Guidance and Recommendations

Developed by the Stage 3 Meaningful Use Public Health Reporting Task Force

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2 Overview

2.1 Background

The Centers for Medicare and Medicaid Services (CMS) published the final rules for Stage 3 Meaningful Use (MU3) and Modifications to Meaningful Use in 2015 through 2017 (Modified Stage 2) in the Federal Register on October 16, 2015. The public health reporting aspects of the rules continue to push local and state Public Health Agencies (PHAs) to enhance their informatics capabilities and establish new or review existing processes with which to receive meaningful use (MU) public health reporting data from Eligible Professionals (EPs) and Eligible Hospitals (EHs) or Critical Access Hospitals (CAHs), collectively referred to as "Providers" in this document.

Key features of Modified Stage 2 and MU3 rules include:

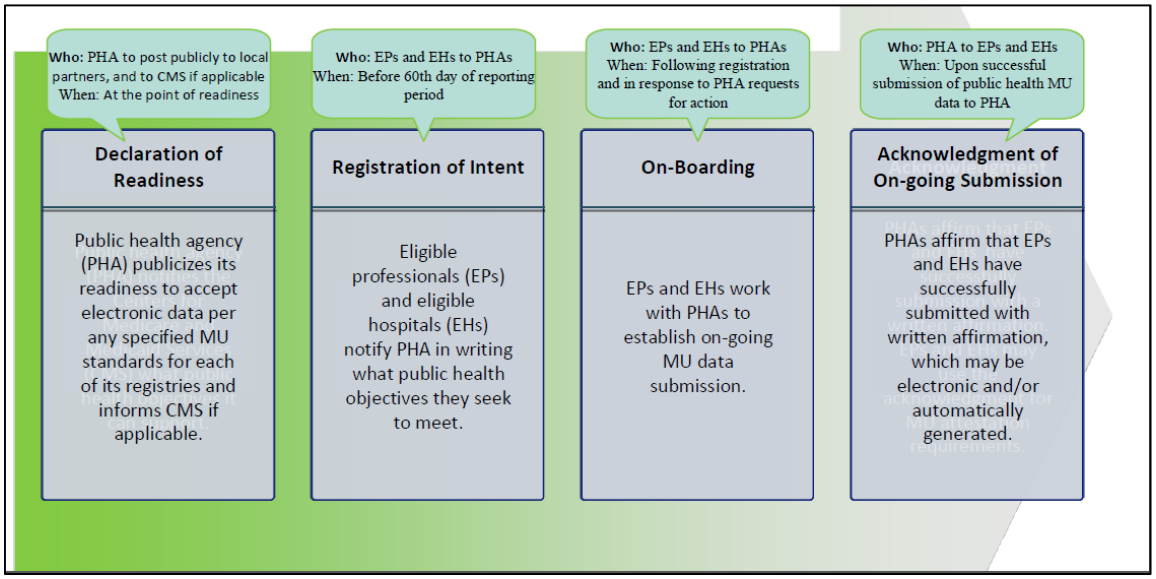
- Aligning all three stages of Meaningful Use into a single program/rule.
  - All Providers would meet MU3 requirements starting in 2018.
  - Phased-in timelines allowing Providers to continue to meet Stage 2 requirements in 2017.
- Aligning reporting periods – calendar year reporting for EPs, EHs and CAHs *(see Appendix C for additional details)*.
  - Full-year reporting periods.
  - In 2016, Providers demonstrating MU for the first time will have a 90-day EHR reporting period. In 2017, Providers in the Medicaid EHR Incentive Program demonstrating MU for the first time and Providers demonstrating MU3 will have a 90-day EHR reporting period.
- Providing simplified public health objectives and measures *(see Appendix A for additional details)*.
  - Modified Stage 2: Objective 10 relates to Public Health Reporting.
    MU3: Objective 8 relates to Public Health and Clinical Data Registry Reporting.
- Describing what constitutes an EP, EH, or CAH being 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.
  - The PH objectives under Modified Stage 2 and MU3 regulations have a certain number of measures that Providers need to attest to or claim exclusion from in order to the meet the MU requirements.
  - In Modified Stage 2 and MU3 final rules, the prior ongoing submission requirement has been replaced with an ''active engagement'' requirement, which will be more aligned with the process Providers undertake to report to a clinical registry or public health agency. ''Active engagement'' means the Provider is in the process of working 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*(see section 4.2 for additional details on Active Engagement)*

PHAs are strongly encouraged, though not required, to support the Modified Stage 2 and MU3 public health measures. These measures represent tremendous opportunities for PHAs to improve their data acquisition and surveillance capabilities. Providers whose public health jurisdictions lack the capacity to support Modified Stage 2 and MU3 measures will qualify to take exclusions from meeting those measures.

Modified Stage 2 and MU3 regulations assume PHAs would continue performing four (4) administrative tasks, which include (see Figure 1):

- Publicizing the PH measures for which the PHA will be ready to accept data and sharing this information with Providers either via the proposed Centers for Medicare & Medicaid (CMS) centralized PHA capacity repository or through their own websites (*Declaration of Readiness process*).
- Providing a method for Providers to register their intent to submit public health data to a PHA for the MU measures (*Registration of Intent process*/*Active Engagement Option 1*).
- Testing and validating data submissions from health care Providers *(On-Boarding process*/ *Active Engagement Option 2).*
- Providing written communication(s) (which may be in electronic format) to health care Providers who are in active engagement with public health. (*Acknowledgement of Ongoing Submission process*/ *Active Engagement Option 3*).

Figure 1: The four administrative tasks for PHAs to support Modified Stage 2 and MU3 Public Health Reporting measures.



The Centers for Disease Control & Prevention (CDC) facilitated the establishment of the Stage 3 MU Public Health Reporting Requirements Task Force (Task Force) with representatives from the public health community, including: State, Local and Tribal Public Health Departments, National Association of County and City Health Officials (NACCHO), Association of State and Territorial Health Officials (ASTHO), Joint Public Health Informatics Taskforce (JPHIT), International Society for Disease Surveillance (ISDS), Council of State and Territorial Epidemiologists (CSTE), North American Association of Central Cancer Registries (NAACCR), American Immunization Registry Association (AIRA), Office of the National Coordinator for Health Information Technology (ONC), and others.

2.2 What guidance is available to help Public Health Agencies (PHAs)?

The Stage 3 MU Public Health Reporting Requirements Task Force has documentation to identify key concepts, task flows, and guidance for PHAs to support MU public health objectives and associated new business processes required for Modified Stage 2 and MU3.

The Task Force has developed or will develop:

- Recommendations to CMS for their proposed centralized PHA capacity repository which will supply Providers with information on their PHA's capacity to accept electronic data for Modified Stage 2 and MU3 public health measures.
- Guidance for PHAs to declare readiness to receive data for Modified Stage 2 in 2015 through 2017 and MU3 in 2017 and 2018, and to facilitate the registration of intent by Providers, on-boarding and ongoing submission of production data, and the ability to provide acknowledgements to Providers.
- Guidance related to transport protocols for the electronic submission of data to PHAs for the MU public health objectives.
- Guidance on how PHAs can leverage the specialized registry reporting measure to obtain case information such as birth defects, traumatic injuries, hearing and vision, and other public health surveillance information.

PHAs across the nation will be able to adopt this guidance according to their jurisdictional needs to implement the processes required for Modified Stage 2 and MU3. This guidance is available on the Stage 3 Meaningful Use Public Health Reporting Task Force web page.

3 Declaration of Readiness

3.1 What does Declaration of Readiness mean?

For Modified Stage 2 and MU3, any PHA that intends to receive electronic data from Providers will need to declare its readiness for receiving such data; otherwise, Providers may claim exclusions from the public health measures. CMS again proposed to support Providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness (see text box below for further details). Earlier, in the Stage 2 final rule (77 FR 54021), CMS noted the benefits of developing a centralized repository where a PHA could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objective and measures. CMS, pursuant to the Paperwork Reduction Act of 1995, published a notice in the Federal Register on February 7, 2014, soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). Based on these efforts, CMS now proposes to move forward with the development of the centralized repository by the start of 2017 calendar year.

The proposed CMS centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level and will thus enable "one-stop shopping" for Providers and vendors seeking information on specific public health jurisdictional readiness to accept reporting for the MU objective. ***However, the PHAs should note that they will need to publicly declare their MU readiness in some fashion (e.g., on the PHA's website) even if CMS does not provide a national repository or until such time as CMS establishes this repository.***

Reference from CMS regulation-

"We also propose to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a PHA could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. We also published, pursuant to the Paperwork Reduction Act of 1995, a notice in the Federal Register on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we now propose moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level."

3.2 What do the regulations say?

The regulations say that PHAs should declare their readiness for each measure under the public health objective for which it will accept MU standards-compliant data from Providers.

For Modified Stage 2, if a PHA has not declared readiness by the first day of a Provider's EHR reporting period, the Provider may be eligible to take an exclusion. The EHR reporting period is the time period through which a Provider seeking MU incentive payments must demonstrate meaningful use of EHR technology *(see Appendix C for additional details).*

Providers need to know on the first day of their EHR reporting period if the PHA has declared readiness, because if the PHA declares readiness on the second day of a Provider's EHR reporting period, the Provider may be eligible to take an exclusion. Since most Providers are on a 12- month reporting period for Program Year 2016,[1] many will be able to take an exclusion for measures that

[1] Starting in 2016, the EHR reporting period for all Providers will be based on the calendar year. The exception is Providers that have not participated in the meaningful use program in a prior year, who are allowed to use any continuous 90-day period.

PHAs have not declared readiness for by January 1, 2016 or earlier.

If a PHA declares readiness for a measure after the beginning of the EHR Reporting period, Providers may still be eligible to meet the measure by registering their intent with the PHA. CMS has clarified that Providers may still register their intent to report with a registry even if that registry has declared their readiness at a point in time after the initial 60 days in the calendar year. This registration of intent would allow the Provider to meet the measure under Active Engagement Option 1. However, a Provider who could report to that registry may still exclude for that calendar year if they had already planned to take an exclusion based on the registry not declaring readiness at the beginning of the Provider's EHR reporting period and not allowing for the Provider's registration of intent within the first 60 days of the reporting period.[2]

For MU3, CMS finalized a modified exclusion that states if a PHA has not declared readiness to accept data for a measure 6 months prior to the start of the Provider's EHR reporting period, (i.e. January 1 of each year beginning in 2018), a Provider can take an exclusion for the measure. CMS believes that modifying the exclusion to request public health agencies or organizations supporting clinical data registries to declare their readiness 6 months ahead of the first day of the EHR reporting period would allow providers adequate notice of public health agencies' and clinical data registries' plans to accept data at the beginning of an EHR reporting period.

The regulations indicate that CMS *anticipates*, but does not commit to, building a centralized repository of PHA readiness information. Regardless, PHAs must officially declare for which of its public health registries it has the capacity to receive information electronically using the standards and specifications prescribed by ONC's health IT certification rules.

Lastly, the regulations say that if CMS does not establish the centralized repository, Providers must determine PHA capacity by working directly with the PHAs to which they report, as they did in Stage 1 and Stage 2 of Meaningful Use. Note that it is not the responsibility of the PHA to track readiness of registries outside their jurisdiction and for which they do not control.

3.3 What does this mean for a Public Health Agency?

A PHA will need to declare which MU public health registries/measures it will support and which ONC-approved standards it will require Providers to use. For MU3, CMS set a deadline for PHAs to publicize their capacity or readiness 6 months before the start of the EHR reporting period.

It is important to note the term capacity as used in the regulations refers to two aspects of readiness: (1) the PHA has the ***technical capacity*** to receive data using the specified standards; and (2) the PHA has the ***administrative [resource] capacity*** to onboard the Provider during the reporting period. Receiving data could mean directly, through a certified HIE, or via a national system such as BioSense 2.0. PHAs with the technical capacity to receive data are encouraged to declare their readiness to receive data even if they have limited administrative capacity. PHAs may be able to use queuing to prioritize Providers for on-boarding and manual processes for tracking and on-boarding to effectively manage the administrative workload. For more information on PHA administrative capacity, please refer to the sections on Registration of Intent, On-Boarding, and Acknowledgements of Submission of Production Data.

[2] From CMS FAQ 14393 - *https://questions.cms.gov/faq.php?id=5005&faqId=14393*

It is not yet known if the CMS repository will actually take shape or how frequently CMS will allow a PHA to update its readiness information. On multiple occasions, this Task Force has recommended to CMS allowing PHAs to periodically update their status.

Key Process Communications:

- Timely submission or posting of PHA declaration of readiness information

3.4 What actions can a Public Health Agency take now?

In some states, both state and local PHAs are accepting MU data submissions from Providers. If the PHA has not already done so, consider convening a cross-agency/cross-program task force to coordinate the planning, implementation, and communications for MU. State and local agency needs, as well as coordinated efforts with Medicaid and state and local HIE and HIT bodies, should be considered to ensure stakeholders are familiar with expectations for PHAs. The information in this document and the other resources listed in the Resources section can help PHAs prepare.

Also, consider developing a MU home page on the PHA's website where Providers can access general information about agency readiness and be directed to more specific information on measures/public health programs the agency supports. One suggestion could be to create a listserv that Providers can subscribe to regarding updates from the PHAs on recommended Provider actions regarding meaningful use, declarations of readiness, changes to program requirements, onboarding, etc.

For example, after communications with a PHA regarding recommended Provider actions under previous regulations, Providers may not visit the relevant jurisdictional web site again, and could potentially assume their actions should remain the same for subsequent Program Years. Due to changes in the regulations over time, PHA recommendations on Provider actions may have changed since the original communication. Providers in that jurisdiction have the potential to be audited, which may result in having their EHR Incentive Program payments recouped.

4 Registration of Intent

4.1 What does Registration of Intent mean?

Providers intending to meet Modified Stage 2 and MU3 public health measures must register their intent to do so with the PHA to which the Provider intends to submit data. Providers must register their intent with the PHA no later than the 60 days after the start of their EHR reporting period or earlier.

The EHR reporting period is the time period through which a Provider seeking MU incentive payments must demonstrate meaningful use of EHR technology. Beginning in 2016, most Providers will have a 12-month EHR reporting period aligned with the calendar year *(see Appendix C for additional details)*.

4.2 What do the regulations say?

Modified Stage 2 and MU3 public health measures require active engagement, meaning the Provider is in the process of working towards sending production data using CEHRT and, as described above, Providers will be contacting PHAs to register their intent to do so. If the PHA has the capacity to accept Providers' data *(see Declaration of Readiness section for additional details)*, a Provider can meet a Modified Stage 2 and MU3 public health measure through the active engagement steps below:

Active Engagement Option 1—Completed Registration to Submit Data: The EP, EH, or CAH registered to submit data with the public health agency or, where applicable, the clinical data registry to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, EH, or CAH is awaiting an invitation from the public health agency or clinical data registry to begin testing and validation. This option allows Providers to meet the measure when the public health agency or the clinical data registry has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Active Engagement Option 2—Testing and Validation: The EP, EH, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the public health agency or, where applicable, the clinical data registry within 30 days; failure to respond twice within an EHR reporting period would result in that Provider not meeting the measure.

Active Engagement Option 3— Production: The EP, EH, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry.

4.3 What does this mean for a Public Health Agency?

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 include:

- PHAs have information on Providers planning to submit data to the PHA for Modified Stage 2 and MU3.
- Providers have the information about the PHA on-boarding process.

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.

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.

4.4 What actions can a Public Health Agency take now?

At a minimum, PHAs should establish a process to register Providers as they contact PHAs to indicate their intent to submit data to meet Modified Stage 2 and MU3 public health measures. Some PHAs may implement a simple registration process (like sending an email to a designated mailbox to begin the registration process) while others may use more elaborate electronic registration and tracking processes. This registration process should entail capturing information on the Provider that will later facilitate on-boarding. This information could vary depending on the type of Provider (e.g., hospitals, group practices, integrated health care delivery networks). It is possible the registration process will need to accommodate Providers at various stages of MU. A detailed list of recommended data elements to capture during Provider registration can be found in a functional requirements document developed by the Task Force.[3] This functional requirements document is intended for a technical audience that might be tasked with developing tools or a system to support the Provider registration processes.

As Providers register, PHAs should consider providing them implementation guides and other guidance to prepare them for on-boarding (*see the sections on On-Boarding and Acknowledgements of Submission of Production Data for additional details*). The PHA could include an invitation to begin on-boarding or information that helps the Provider know when to expect this invitation.

PHAs should consider establishing an MU Coordinator (see CDC Director's Guidance on MU Coordinator Role) or other dedicated resource(s) to lead and coordinate the PHA's response to the MU requirements. It is also recommended that the PHA work with a designated point of contact representing the Provider, which could be an individual professional, hospital, group practice, or integrated delivery network. PHAs should leverage the Regional Extension Centers (RECs) serving Providers in their jurisdiction. For example, RECs can help Providers understand the requirement to register their intent with the PHA and successfully complete the registration process. If the PHA has not already done so, the PHA should consider convening a cross-agency/cross-program task

[3] This document is available on the Task Force's community site on Center for Disease Control and Prevention EHR Meaningful use website at: (http://www.cdc.gov/ehrmeaningfuluse/).

force to coordinate the planning, implementation, and communications for Modified Stage 2 and MU3.

5 On-Boarding

5.1 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. Each 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.[4]

5.2 What do the regulations say?

The original Stage 2 MU regulations discussed the requirement to submit information to a PHA in accordance with applicable law and practice:

> *… We believe that the requirement to submit information would be under applicable law, the agreements between the Provider and PHA, or through Meaningful Use which requires submissions except where prohibited, so it is not necessary for Meaningful Use to monitor the already mandated submission.*[5]

The MU public health objective for Modified Stage 2 and MU3 continue to include the phrases "except where prohibited" and "in accordance with applicable law and practice." Per information provided in the original MU Stage 2 rule, the phrase "except where prohibited" is meant to encourage reporting to a PHA by a Provider even when there is no explicit reporting requirement in that jurisdiction. For example, voluntary participation in a registry does not require authorization to do so. The phrase "in accordance with applicable law and practice" allows PHAs to use their existing laws, regulations, and business practices in structuring the data reported from Providers to the PHA. In addition, this phrase also ensures MU does not preempt applicable state or local laws that govern reporting to the PHA.[6]

A PHA may designate or authorize a third party, such as a Health Information Exchange (HIE), to serve as an ongoing destination or conduit for a Provider's MU data reporting. If, however, this intermediary transforms the Provider's data or message format to meet MU requirements, then the third party is not functioning merely as a conduit but rather as an extension of the Provider's EHR. In such cases, the HIE must use CEHRT to transform the data, and Providers must attest to the PH measure using that certified module. Providers must ensure their submissions reach the PHA, except in cases where the PHA has explicitly stated submission to the HIE satisfies reporting requirements.

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[4] From the CMS Stage 3 and Modifications Final Rule 80 FR 62863 - https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

[5] From the CMS Stage 2 Final Rule 77 FR 54022 - *http://www.federalregister.gov/a/2012-21050/p-1021*

[6] From the CMS Stage 2 Final Rule 77 FR 54022 - *http://www.federalregister.gov/a/2012-21050/p-1022*

5.3 What does this mean for Public Health Agencies?

PHAs will need to track the status of Providers throughout the on-boarding processes. This tracking process should begin when the Provider registers their intent to meet Modified Stage 2 and MU3 public health measures. After registering, a Provider's status could be described as a series of engagement steps. As examples, these engagement steps could include "waiting for on-boarding invitation," "invited to on-board," "currently on-boarding," or "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.

Providers must still follow applicable state or local laws for reporting to a PHA. Modified Stage 2 and MU3 do not preempt applicable state or local laws that govern reporting to the PHA. In some jurisdictions, existing public health reporting rules and regulations may reflect more stringent requirements than the active engagement requirements outlined in the Modified Stage 2 and MU3 regulations. In those jurisdictions, achieving active engagement with a PHA to satisfy a Modified Stage 2 and MU3 could enable a Provider to fulfill some of the reporting requirements to the PHA mandated by applicable state or local laws.

A PHA will likely be on-boarding Providers who intend to meet Modified Stage 2 public health reporting measures and also those who intend to meet MU3 public health reporting measures in the future. The Task Force recommends that the PHA's on-boarding process is able to accommodate both Modified Stage 2 and MU3.

PHAs should consider establishing a MU Coordinator (see CDC Director's Guidance on MU Coordinator Role) or other dedicated resource(s) to lead and coordinate the PHA's response to the Meaningful Use requirements. It is recommended that the PHAs work with a designated point of contact representing the Provider, or in the case of group practices and integrated delivery networks, collections of Providers. The Provider's point(s) of contact would be the recipient of documentation that is needed for attestation and audit for the EHR Incentive Program. During the on-boarding process, Providers' points of contact may work directly with PHA subject matter experts (SME) more familiar with the data and standards for a particular measure.

PHAs are not responsible for verifying if Providers are using CEHRT or whether Providers are meeting CMS deadlines as part of the MU attestation process. Furthermore, PHAs are not expected to be the arbiters of Providers' achievement of MU or entitlement to incentive payments. Rather, PHAs are expected to document Providers' activities as they register their intent to on-board, respond to the PHA's requests during on-boarding, and work with the Provider to achieve the Provider's submission of production data. The communications a PHA sends to Providers or publishes will be evidence Providers can use when attesting to the EHR Incentive Program or if audited by CMS or the State Medicaid Program.

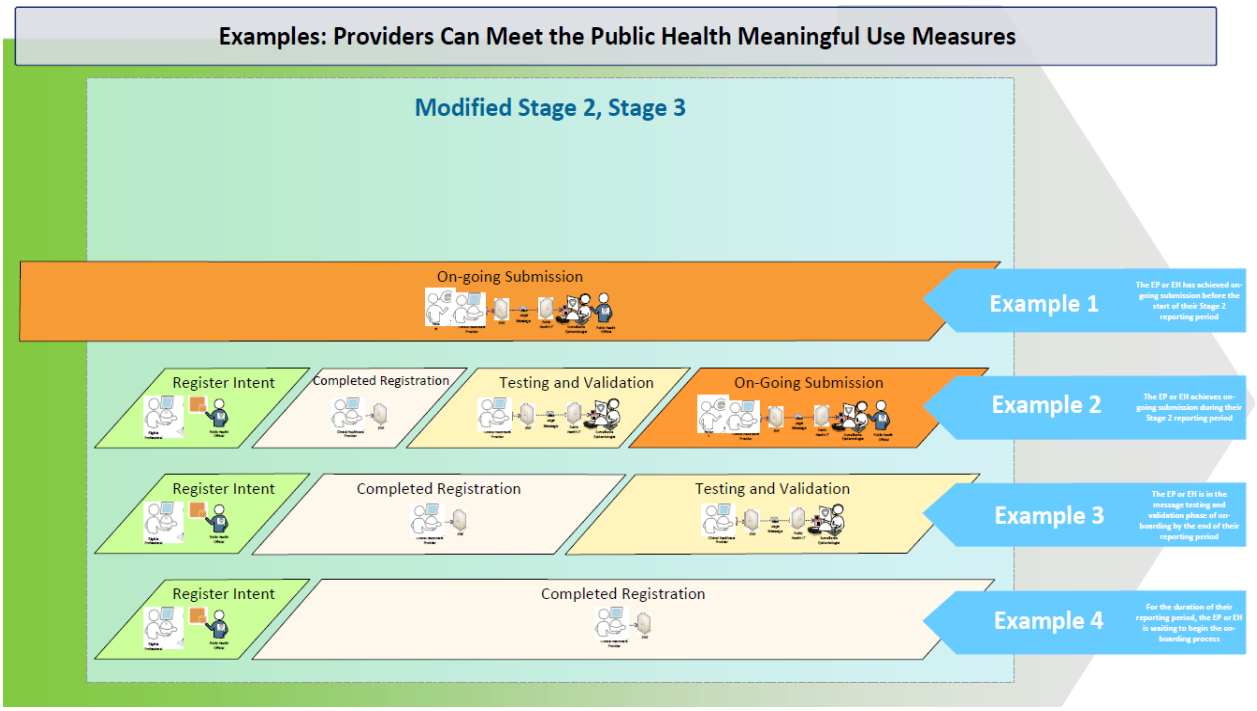

Figure 2: Graphic representation of four ways an EP or EH/CAH can meet the on-going submission measure for Modified Stage 2.

Key Process Communications:

- PHA written requests to take action sent to Providers that have registered their intent to submit data for Modified Stage 2 and MU3 measures. Examples of written requests include, but are not limited to: invitation to begin on-boarding, requests to complete on-boarding steps, and requests for corrective action during message testing and validation. Members of the Stage 3 Meaningful Use Public Health Reporting Task Force created templates for MU related communications between PHAs and MU eligible Providers, which are located at: (See PHA to Provider communication templates).
- Provider's replies and responses to the PHA's written requests to take action.

5.4 What actions can a Public Health Agency take now?

PHAs should consider providing on-boarding guidance for Providers when they register their intent to submit data. This guidance can include implementation guides, a PHA's transport method requirements, and message validation resources. The goal of successful on-boarding is high quality, complete, and timely data useful for public health purposes, and it is critical for Providers to follow PHA's implementation guides and other on-boarding guidance to achieve this.

PHA MU coordinators should consider holding internal meetings with PHA SMEs for immunization registry reporting, syndromic surveillance reporting, electronic reportable laboratory result reporting, case reporting, and other specialized registries. During the on-boarding process, the MU coordinator could act as a liaison between the Provider and the PHA programs to which the Provider is attempting to submit data. The MU coordinator could track the communications between the Provider and PHA, while the PHA SMEs could provide detailed technical guidance during the testing and validation of data submissions.

6 Acknowledgements of Submission of Production Data

6.1 What are Acknowledgements of Submission of Production Data?

For Modified Stage 2 and MU3, Providers should be working with the PHA to achieve ongoing submission of production data. Acknowledgements of submission of production data are the official communications sent from PHAs to Providers that affirm a Provider has successfully submitted public health data for Modified Stage 2 and MU3 public health measures. 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.[7]

6.2 What do the regulations say?

Modified Stage 2 and MU3 regulations state that PHAs will provide written communications to affirm a Provider has submitted relevant public health data to the PHA.[8] In the event of an audit, Providers will use this written PHA communication to substantiate their attestation to CMS that they met Modified Stage 2 and MU3 public health measures. The regulations do not specify message content or format for this written communication but do indicate that electronic formats are permissible.

6.3 What does this mean for a Public Health Agency?

The Modified Stage 2 and MU3 regulations allow PHAs to determine the format and medium they want to use to provide a written communication to the Provider to acknowledge/affirm the Provider has submitted the relevant public health data. This means PHAs need to determine communication content and format as well as how to issue these written communications. Options PHAs should consider for this written communication include, but are not limited to:

- Emailing a message to the Provider
- Mailing a letter to the Provider
- Publishing the names of Providers on the PHA's website
- Using automated acknowledgements generated by systems that are receiving the Provider's data (e.g. HL7 acknowledgement (ACK) messages from immunization submissions).

Identifying and assessing the potential issues, challenges, and limitations associated with any option should be thoroughly considered by the PHA prior to making a decision.

For the content, PHAs should acknowledge that a Provider submitted the relevant public health data in production to the PHA, the type of data (i.e. immunizations, cancer cases, syndromic surveillance, ELR, case reporting, etc., and the date but **should not** state that a Provider has achieved MU or met the public health measure. Determinations regarding attestation will be made by CMS or the State Medicaid Program.

As described in the *Registration of Intent* and *On-Boarding* sections, in order for PHAs to be effective in their role, they should develop processes and tools to track any MU-related communications with Providers. These communications will include confirmation that Providers have registered their

[7] From the CMS Stage 3 and Modifications Final Rule 80 FR 62863 - *https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications*

[8] From the CMS Stage 2 Final Rule 77 FR 54022 - *http://www.federalregister.gov/a/2012-21050/p-1019*

intent to submit data to the PHA, invitations to Providers to begin on-boarding, requests for action Providers need to take during on-boarding, and acknowledgements that Providers have successfully submitted data. PHAs should inform the Providers to retain the PHA communications they receive in case they are audited by CMS or the State Medicaid Program.

Key Process Communications:

- PHAs sending a Provider written communication (which may be in electronic format) to affirm the Provider has submitted the relevant public health data to the PHA.

6.4 What actions can a Public Health Agency take now?

PHAs will need to determine the type, format, and content of the acknowledgements to provide for each of the Modified Stage 2 and MU3 public health measures. In some states, both state and local PHAs are accepting MU data submissions from Providers. If the PHA has not already done so, consider convening a cross-agency/cross-program task force to coordinate the planning, implementation, and communications for Modified Stage 2 and MU3. State and local agency needs, as well as coordinated efforts with Medicaid and state and local HIE and HIT bodies, should be considered to ensure stakeholders are familiar with expectations for PHAs. The fact sheets and other resources listed in the Other Resources section can help PHAs prepare.

7 Specialized Registries

Under Modified Stage 2, the Specialized Registry Reporting measure continues to encompass both public health registries and clinical data registries, as it did under the Stage 2 specialized registry data submission objective. New in Modified Stage 2, this measure is now available for EHs and CAHS, not just EPs (although the Cancer Reporting option remains only available for EPs).

7.1 What are Specialized Registries?

CMS has agreed that a variety of registries may be considered specialized registries. This variety allows Providers the flexibility to report to a registry that is most helpful to their patients. CMS has supported inclusion of a variety of registries under the specialized registry measure, including Prescription Drug Monitoring Program reporting and electronic case reporting.[9]

7.2 What do the regulations say?

For meaningful use purposes, CMS has specifically declared how Providers can meet the Specialized Registry Reporting measure. More information can be found at CMS FAQ 13653.

In the previous Stage 2 MU final rule, cancer registry reporting was a separate objective. Under Modified Stage 2, it now falls under the Specialized Registry Reporting measure and is only available for eligible professionals for MU purposes. Cancer reporting is the only registry under this measure that has specific standards and certification criteria required to meet the CEHRT definition, the HL7 CDA.[10]

For MU3, the Specialized Registry Reporting measure will be split into two separate measures (Public Health Registry Reporting and Clinical Data Registry Reporting) with the following definitions:

- A public health registry is defined as one that is administered by, or on behalf of, a local, state, territorial, or national public health agency and which collects data for public health purposes.
- A clinical data registry is defined as one that records information about the health status of patients and the health care they receive over varying periods of time and is administered by, or on behalf of, other non-public health agency entities.

For the purposes of MU3, cancer case reporting for eligible professionals will fall under the Public Health Registry Reporting measure.

[9] From the CMS Stage 3 and Modifications Final Rule 80 FR 62823 - *https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications*

[10] The ONC-adopted standard for cancer registry reporting using 2014 Edition CEHRT is Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries August 2012 and using 2015 Edition CEHRT is *HL7 Implementation Guide for CDA © Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Release 1.1* (See *http://www.cdc.gov/ehrmeaningfuluse/cancer.html*).

7.3 What does this mean for Public Health Agencies?

Declaring relevant public health registries as available to meet the Specialized Registry Reporting measure is a great way to encourage Providers to supply data to PHA programs. If a PHA intends to declare a registry as a Specialized Registry for MU purposes, they would have to:

- Be using the data gathered by the registry to improve population health outcomes or for a public health purpose.
- Be able to receive electronic data generated from CEHRT.
- Make publicly available a declaration of readiness to accept data as a specialized registry (see Declaration of Readiness section).[11]
- Specify the means of file transmission. The electronic file can be sent to the receiving entity through any appropriately secure mechanism including, but not limited to, a secure upload function on a web portal, SFTP, or Direct. Manual data entry into a web portal would not qualify for submission to a specialized registry.
- Have the following processes in place for Providers:
    - Registration of intent process,
    - Test and validation process,
    - Process to move Provider's data submission into production
- Be able to provide appropriate documentation for the Provider regarding Provider's Active Engagement status (see section 4.2).

Certified EHR technology is not required for all specialized registry reporting for Modified Stage 2, but EHR technology certified to the 2014 Edition or 2015 Edition may be used.[12] For registries without specific standards under the 2014 Edition, PHAs may allow Providers to use electronic submission methods, which are not included in the specifications of CEHRT to meet the requirements for the specialized registry measures. ONC will consider adoption of standards and implementation guides in future rulemaking. Should these standards subsequently be finalized, they may then be adopted as part of the CEHRT definition as it relates to meeting the Public Health Registry Reporting measure through future rulemaking for the EHR incentive programs in MU3.

If a Provider achieved Active Engagement Option 3: Production, including production data submission with a specialized registry in a prior year under the applicable requirements of Modified Stage 2, the Provider may count the specialized registry under the Public Health Registry Reporting measure in MU3 as long as there are not standards and requirements referenced in the ONC 2015 Edition regulations for Public Health and Clinical Data Registry Stage 3 measures. A PHA that previously declared readiness for a public health registry with applicable 2015 Edition standards and requirements would need to be able to adopt any new standards to continue its declaration of readiness. Any Providers that previously achieved production data submission status would need to have CEHRT that complies with the new standards to meet the measure. PHAs should keep this in mind when deciding whether or not to declare readiness to accept data for certain registries under Modified Stage 2.

[11] From CMS FAQ 13653 - *https://questions.cms.gov/faq.php?id=5005&faqId=13653*

[12] From the CMS Stage 3 and Modifications Final Rule 80 FR 62879 - *https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications*

7.4 What actions can a Public Health Agency take now?

CMS has declared that Providers may still register their intent to report with a registry even if that registry has declared their readiness at a point in time after the initial 60 days in the calendar year. This registration of intent would allow the Provider to meet the measure under Active Engagement Option 1. However, a Provider who could report to that registry may still exclude for that calendar year if they had already planned to exclude based on the registry not declaring readiness at the beginning of the Provider's EHR reporting period and not allowing for the Provider's registration of intent within the first 60 days of the reporting period.[13]

In MU3, PHAs need to make a public declaration of readiness 6 months prior to a Provider's EHR reporting period. If a Provider has the necessary CEHRT to submit data to a public health registry, but the PHA has not declared readiness 6 months in advance, the Provider may be able to take an exclusion to the measure.

PHAs are not responsible for tracking and making information available to Providers on clinical data repositories that have declared readiness to accept data for meaningful use. At this time, the Task Force is not aware of any available listing of clinical data registries sponsored by national societies or other non-public health state programs that are accepting data from Providers for meaningful use. Providers should check with the national and state specialty/medical societies covering the Provider's scope of practice with which they are affiliated and have a membership, as well as any CMS documents or FAQs for guidance.

If PHAs do become aware of other public health or clinical data registries available to Providers to meet the meaningful use measures, the PHA could provide a link to the information about the other registries on the PHA's meaningful use webpage/website. The PHA could also have a disclaimer stating the PHA does not have any responsibility for registering or assisting Providers with onboarding to those other registries.

The PHA could also consider reaching out to the Prescription Drug Monitoring Program, if it is not located within the public health agency, to establish a relationship and share information about the meaningful use specialized registry measure.

The CDC EHR Meaningful Use website has a listing with links to Jurisdiction Meaningful Use webpages at http://www.cdc.gov/EHRmeaningfuluse/Jurisdiction.html.

Also, working in collaboration with the MU PH Reporting Requirements Task Force, the Association of Public Health Laboratories (APHL) has compiled an unofficial listing of state-specific Stage 2 Public Health reporting readiness based on information from public health agency websites. The APHL list can be accessed at
http://www.aphl.org/aphlprograms/informatics/Pages/MU2PHAReadiness.aspx.

[13] From CMS FAQ 14393 - *https://questions.cms.gov/faq.php?id=5005&faqId=14393*

8 Other Resources: Where to go for resources and additional information?

Online Resources

- CDC Meaningful Use web site (www.cdc.gov/ehrmeaningfuluse)
- CDC Immunization web site (http://www.cdc.gov/vaccines/programs/iis/meaningful-use/index.html)
- CDC National Program of Cancer Registries (NPCR) website at: http://www.cdc.gov/cancer/npcr/meaningful_use.htm
- CMS Meaningful Use web site (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html)
- ONC web site (http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2)
- ONC Interoperability and Public Health training course (http://www.healthit.gov/public-course/interoperability-public-health/course_HITRC/index.html)
- Stage 2 MU PH Reporting Requirements Task Force community site

Organizations

- Public health association(s)
- ONC Regional Extension Center(s)

Internal PHA/State Resources

- State Health IT Coordinator
- MU Coordinator

9 Appendix A – Public Health Objective and Measure Details

Starting in 2015, there is one consolidated public health objective, requiring the Provider be in active engagement with a PHA to submit electronic public health data using certified EHR technology (CEHRT), except where prohibited and in accordance with applicable law and practice. This one public health objective consists of multiple measures.

9.1 Public Health Measures in Modified Stage 2

To meet Modified Stage 2 Objective 10: Public Health Reporting, EPs must meet two measures, and EHs and CAHs must meet three measures.

Under the Public Health Reporting Objective, EPs in Modified Stage 2 have three measure options:

- Measure 1 – Immunization Registry Reporting: The EP is in active engagement with a public health agency to submit immunization data.
- Measure 2 – Syndromic Surveillance Reporting: The EP is in active engagement with a public health agency to submit syndromic surveillance data.
- Measure 3* – Specialized Registry Reporting: The EP is in active engagement to submit data to a specialized registry.

** For Measure 3, an EP may report to more than one specialized registry and may count specialized registry reporting more than once to meet the required number of measures.*

Note: For EPs, an exclusion for a measure does not count toward the total of two measures. If an EP excludes from a measure, they must meet or exclude from the remaining measures in order to meet the objective. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than two, the EP can meet the objective by meeting the one remaining measure available to them. If no measures remain available, the EP can meet the objective by meeting the requirements for exclusion from all three measures.

In Modified Stage 2, under the Public Health Reporting Objective, EHs and CAH have four measure options:

- Measure 1 – Immunization Registry Reporting: The EH or CAH is in active engagement with a public health agency to submit immunization data.
- Measure 2 – Syndromic Surveillance Reporting: The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data.
- Measure 3 – Specialized Registry Reporting: The EH or CAH is in active engagement to submit data to a specialized registry.
- Measure 4 – Electronic Reportable Laboratory Result Reporting: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory (ELR) results.

** For Measure 3, an EH or CAH may report to more than one specialized registry and may count specialized registry reporting more than once to meet the required number of measures.*

Note: For EHs and CAHs, an exclusion for a measure does not count toward the total of three measures. Instead to meet this objective, an EH or CAH would need to meet three of the total number of measures available to them. If the EH or CAH qualifies for multiple exclusions and the total number of remaining measures available to the EH or CAH is less than three, the EH or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. If no measures remain available, the EH or CAH can meet the objective by claiming applicable exclusions for all measures.

Modified Stage 2: Objective 10: Public Health Reporting	Eligible Professionals	Eligible Hospitals and CAH
Total number of measures Provider must meet	2*	3*
	Max times measure can be counted by EP	Max times measure can be counted by EH/CAH
Measure 1: Immunization Registry Reporting	1	1
Measure 2: Syndromic Surveillance Reporting	1	1
Measure 3: Specialized Registry Reporting**	2	3
Measure 4: Electronic Reportable Laboratory Results	N/A	1

**Alternate exclusions may apply. See Appendix B for additional details.*
***For Measure 3, a Provider may report to more than one specialized registry and may count specialized registry reporting more than once to meet the required number of measures for the Public Health Reporting objective.*

9.2 Public Health Measures in MU3

Providers are allowed to choose to meet MU3 objectives optionally in 2017, but they are required to meet MU3 objectives for 2018 and beyond. To meet MU3, Objective 8: Public Health and Clinical Data Registry Reporting, EPs must meet two measures, and EHs and CAHs must meet four measures.

EPs attesting to MU3 (optionally in 2017 or in 2018 and beyond) have four measure options:

- Measure 1 – Immunization Registry Reporting: The EP 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).
- Measure 2 – Syndromic Surveillance Reporting: The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.
- Measure 3 – Electronic Case Reporting: The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.
- Measure 4 – Public Health Registry Reporting: The EP is in active engagement to submit data to public health registries.
- Measure 5 – Clinical Data Registry Reporting: The EP is in active engagement to submit data to a clinical data registry.

EHs and CAH attesting for MU3 (optionally in 2017 or 2018 and beyond) have six measure options:

- Measure 1 – Immunization Registry Reporting: The EH 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).

- Measure 2 – Syndromic Surveillance Reporting: The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care or emergency department setting.
- Measure 3 – Electronic Case Reporting: The EH or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.
- Measure 4 – Public Health Registry Reporting: The EH or CAH is in active engagement to submit data to public health registries.
- Measure 5 – Clinical Data Registry Reporting: The EH or CAH is in active engagement to submit data to a clinical data registry.
- Measure 6 – Electronic Reportable Laboratory Result Reporting: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory (ELR) results.

Stage 3: Objective 8: Public Health and Clinical Data Registry Reporting	**Eligible Professionals**	**Eligible Hospitals and CAH**
Total number of measures Provider must meet	2	4
	Max times measure can be counted by EP	Max times measure can be counted by EH/CAH
Measure 1: Immunization Registry Reporting	1	1
Measure 2: Syndromic Surveillance Reporting	1	1
Measure 3: Electronic Case Reporting	1	1
Measure 4: Public Health Registry Reporting*	2	4
Measure 5: Clinical Data Registry Reporting*	2	4
Measure 6: Electronic Reportable Laboratory Results	N/A	1

**For Measures 4 and 5, a Provider may report to more than one public health and/or clinical data registry and may count public health and/or clinical data registry reporting more than once to meet the required number of measures for the Public Health and Clinical Data Registry Reporting objective.*

10 Appendix B – Alternate Exclusions

CMS has declared through FAQ 12985 and 14401 the Alternate Exclusions for Providers attesting in Program Years 2015 and 2016.

10.1 Providers attesting in Program Year 2015

EPs scheduled to be in Stage 1 must attest to at least 1 measure from the Public Health Reporting Objective Measures 1-3.

- May claim an Alternate Exclusion for Measure 1, Measure 2, or Measure 3.
- An Alternate Exclusion may only be claimed for up to two measures, then the Provider must either attest to or meet the exclusion requirements for the remaining measure.

EPs scheduled to be in Stage 2 must attest to at least 2 measures from the Public Health Reporting Objective Measures 1-3.

- May claim an alternate exclusion for Measure 2 or Measure 3 (Syndromic Surveillance Measure or Specialized Registry Reporting Measure) or both.
- An Alternate Exclusion may only be claimed for up to two measures, then the Provider must either attest to or meet the exclusion requirements for the remaining measure.

EHs/CAHs scheduled to be in Stage 1 must attest to at least 2 measures from the Public Health Reporting Objective Measures 1-4.

- May claim an Alternate Exclusion for Measure 1, Measure 2, Measure 3, or Measure 4.
- An Alternate Exclusion may only be claimed for up to three measures, then the Provider must either attest to or meet the exclusion requirements for the remaining measure.

EHs/CAHs scheduled to be in Stage 2 must attest to at least 3 measures from the Public Health Reporting Objective 10 Measures 1-4.

- May claim an alternate exclusion for Measure 3 (Specialized Registry Reporting Measure)
- An Alternate Exclusion may only be claimed for up to one measure, then the Provider must either attest to or meet the exclusion requirements for the remaining measures.

10.2 Providers attesting in Program Year 2016

EPs scheduled to be in Stage 1 and Stage 2 must attest to at least 2 measures from the Public Health Reporting Objective Measures 1-3.

- May claim an Alternate Exclusion for Measure 2 and Measure 3 (Syndromic Surveillance and Specialized Registry Reporting).
- An Alternate Exclusion may only be claimed for up to two measures, then the Provider must either attest to or meet the exclusion requirements for the remaining measure.

EHs/CAHs scheduled to be in Stage 1 or Stage 2 must attest to at least 3 measures from the Public Health Reporting Objective Measures 1-4.

- May claim an Alternate Exclusion for Measure 3 (Specialized Registry Reporting)
- An Alternate Exclusion may only be claimed for one measure, then the Provider must either attest to or meet the exclusion requirements for the remaining measures.

11 Appendix C – EHR Reporting Period

In 2015, the EHR reporting period for all Providers will be based on the calendar year.

- In 2015 only, the EHR reporting period for all Providers will be any continuous 90-day period.
- EPs may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015.
- EHs and CAH's may select an EHR reporting period of any continuous 90-day period from October 1, 2014 to December 31, 2015.

Beginning in 2016, the EHR reporting period for all returning participants is a full calendar year from January 1, 2016, through December 31, 2016. However, EPs, EHs and CAHs that are new participants demonstrating MU for the first time are allowed an EHR reporting period of any continuous 90-day period within the calendar year.

In 2017, the EHR reporting period is a full calendar year for all Providers; however, participants in the Medicaid EHR Incentive Program demonstrating MU for the first time and all Providers who choose to implement MU3 are allowed any continuous 90-day reporting period within the calendar year.

In 2018 and beyond, the EHR reporting period is a full calendar year for all Providers; however, participants in the Medicaid EHR incentive demonstrating MU for the first time are allowed any continuous 90-day reporting period within the calendar year.