Friday, May 29, 2015

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

Agency/Docket Number CMS-3310-P

Submitted electronically through http://regulations.gov

Dear Centers for Medicare & Medicaid Services:

This letter contains comments and recommendations from the Joint Public Health Informatics Taskforce (JPHIT), a consortium of nine public health associations created to improve population health through informatics. These recommendations are coordinated and harmonized across the associations, and represent a unified public health voice on proposed rules, “Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3.” Our comments concern proposed Objective 8: Public Health and Clinical Data Registry Reporting. JPHIT associations may also comment independently in ways that reflect their unique membership expertise and perspectives.

Stage 3 of Meaningful Use (MU) is an opportunity to build upon the significant progress made in the use of electronic health record technology for improvements in public and population health. JPHIT applauds the proposed clarifications and expansions in public health reporting measures for Stage 3. Continued support through MU for electronic public health reporting is crucial to the success of state, territorial, local, and tribal (STLT) public health system modernization efforts.

JPHIT believes that CMS can significantly improve the Stage 3 rules to better support the current efforts of STLT public health agencies (PHAs), EPs, EHs and CAHs to build and maintain electronic public health reporting relationships. We recommend several changes to the proposed rule in detail on the following pages.

The public health community is committed to being as responsive as it can to the pressing needs of the Meaningful Use programs. The lack of dedicated funding for PHAs to upgrade information systems and add staff is a very real challenge. Since Medicaid funding for infrastructure is one of the few sources available to PHAs, we asked for your continued support in making that funding mechanism available, in persuading state Medicaid programs to be open to collaborating with PHAs, and in any other actions CMS can take to reduce barriers to use of this funding to build public health information infrastructure.
We appreciate your consideration of these comments and welcome you to contact Charlie Ishikawa, JPHIT Executive Secretary (cishikawa@jphit.org) if you require any additional information.

Sincerely,

Joe Gibson, PhD
JPHIT Co-Chair, NACCHO representative

Stephanie Mayfield Gibson, MD, FCAP
JPHIT Co-Chair, ASTHO Representative

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- Charlie Ishikawa, JPHIT Executive Secretary
JPHIT Comments & Recommendations on CMS Proposals for MU Stage 3, Objective 8
Public Health and Clinical Data Registry Reporting

Reference: 80 FR 16762 - 80 FR 16763

Continued inclusion of public health reporting
We are pleased to see continued support for core public health data exchange transactions among healthcare providers and public health agencies (PHA) in Stage 3. Such transactions are essential to realizing public and population health improvements through the HITECH Act.

Split specialized registries into two separate measures: Public health registries, and clinical data registries.
JPHIT understands and appreciates the motivation to streamline reporting and support the ability for a wide diversity of providers to meet MU criteria in the consolidated “Public Health and Clinical Data Registry Reporting” objective. However, the final rule must be clarified to ensure that the progress made by providers, hospitals, and public health agencies (PHAs) for core public health reporting measures under Stage 1 and 2 will continue in Stage 3. Immunization registry reporting, syndromic surveillance, case reporting, and electronic laboratory reporting support core public health functions and data needs. Stage 3 should not create competition among the jurisdictional agencies and programs for EHR data, nor should it result in providers discontinuing reporting relationships established through Stage 1 and 2 efforts. We elaborate on this concept, and suggest alternatives in subsequent comments.

Overview of Proposed Objective 8
Reference: 80 FR 16763 - 80 FR 16763
Replacement of "on-going" submission with "active engagement"
We support describing the Objective 8 requirement as “active engagement.” Replacing "on-going submission" with "active engagement" is an improvement, but the requirement needs further clarification to sufficiently describe the necessary steps for building and maintaining useful public health data exchanges among healthcare providers and public health agencies (PHAs).

Definition of "active engagement"
We recommend two actions to further clarify the definition.

First, the regulation should state a clear definition for active engagement that requires providers, and their EHR vendors, to not only respond to requests for changes, but to ensure that actual progress is made on outstanding issues raised by the PHA. PHAs should also have the authority to determine if an EP, EH or CAH, and their vendors, are genuinely responsive or not.

Second, the regulation should define “production data” to promote the submission of data that are of sufficient quality for public health use. Specifically, "production data" should be defined as complete and timely data that conform to jurisdictional laws and practices.

Re-registration for reporting periods
For immunization registry reporting (measure 1), where the proposed Stage 3 rule adds new functionality that was not present in the Stage 2 rule, it is not clear whether the EP or hospital that registered intent to send to meet Stage 2 would still need to register intent to meet the new measure. Planning for public health agencies would be simplified by clarifying whether an EP or hospital would still need to register intent at least once with respect to the new requirements.
Centralized Readiness Repository
Reference: 80 FR 16763

Centralized repository use
We applaud CMS’s intent to build a centralized repository for PHA to more efficiently communicate the measures that EPs, EHs, and CAHs should meet for objective 8.

Centralized repository structure
JPHIT recommends that CMS refer to the work of the CDC Meaningful Use Stage 2 Task Force and the Association of Public Health Laboratories when developing functional requirements for this repository. JPHIT recommends that PHA MU Coordinators should have direct access to this system to ensure that readiness information is as accurate and up-to-date as possible for all jurisdictions. In addition, the readiness by PHA should allow granularity by specialty, especially for syndromic surveillance. For example, a PHA should be able to state in this repository from which specialties they are accepting syndromic surveillance data.

Proposed Objective 8 Measures
Reference: 80 FR 16763 - 80 FR 16764

Proposal for Stage 3 public health objective
Stages 1 and 2 of MU have enabled public health to make valuable progress in engaging with providers and hospitals to submit standardized, electronic data on immunizations, syndromic surveillance, and reportable laboratory results. PHAs have also invested significant time and resources in educating and onboarding providers for the MU public health objectives. By incentivizing providers and hospitals to work with their PHAs to submit data, stages 1 and 2 are promoting the reporting coverage and strengthening clinical and public health care relationships.
It is vital that CMS continue to emphasize the core public health reporting measures of immunization registry reporting, syndromic surveillance, and electronic laboratory reporting. The progress made through stages 1 and 2, with substantial investments of provider and PHA effort, rely on a stage 3 rule that continues to promote reporting data to public health agencies. Building data reporting connections with providers and hospitals requires significant time to attain production-quality data exchange. Communication and active engagement between EPs/EHs and PHAs are essential. Furthermore, these connections require maintenance as technologies change and evolve. As an ongoing activity, public health reporting is unlike other MU objectives that become “topped out.”

As written, the proposed rule reintroduces optionality for these core public health reporting measures that were required in Stage 2 and creates competition among these core measures and reporting to PHRs and CDRs. JPHIT is concerned that this proposal would undermine progress on those core reporting measures by allowing providers to meet the objective without engaging their local, state, or territorial PHA. In the proposed rule, providers could meet the objective solely through reporting to PHRs, which may be managed by federal health agencies, and CDRs, which are not managed by public health at all. CDRs also have less clearly defined standards for reporting, which may present a simpler option for providers than submitting data to a PHA according to stricter standards and requirements.

We urge CMS to modify the language in the final Stage 3 rule to ensure that essential public health reporting needs remain the focus of this objective while still accommodating the needs of diverse providers and exploring the potential value of CDRs.

We propose retaining the concept of mandatory “core” measures from MU Stages 1 and 2 and incorporating it into the proposed consolidated structure for Objective 8 in Stage 3 (see example Table 1). In this approach, EPs would still be required to meet three public health measures as proposed, but measures 1 and 3 (i.e., immunization registry reporting and case reporting) would be mandatory. If an EP qualifies for an exclusion to measures 1 or 3, they could then choose from the remaining measures to meet the objective. In a similar way, we propose that EHs and CAHs still be required to meet four measures, with measures 1, 2, 3, and 6 (i.e.,
immunization registry reporting, syndromic surveillance, case reporting, and electronic reportable laboratory results) considered mandatory. If an EH/CAH qualifies for an exclusion to any of the mandatory measures, they could choose to meet the measures for reporting to PHRs and CDRs as needed.

Table 1: A proposed modification to the proposed rule for objective 8. Under this modification, “core” measures for public health agencies would be mandatory, and the proposed total measure count approach would be preserved. For EPs, for each measure 1, 2 or 3 exclusion an EP may attest to Measure 4 or 5; e.g., if EP has an exclusion to Measure 2 and not for Measure 1 and 3, then the EP may do either Measure 4 or 5 one time to reach the total 3 measures for the objective. For EHs and CAHs, for each measure 1, 2, 3 or 4 exclusion an EH or CAH may attest to Measure 4 or 5; e.g., if EH has an exclusion to Measure 3 and 6, and not for Measure 1 and 2, then the EH may do either Measure 4 or 5 once to reach the total 4 measures for the objective.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Maximum number of times measure may count toward the objective</th>
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<tbody>
<tr>
<td>Measure 1 – Immunization Registry Reporting</td>
<td>EP: Mandatory</td>
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<tr>
<td></td>
<td>EH or CAH: Mandatory</td>
</tr>
<tr>
<td>Measure 2 – Syndromic Surveillance Reporting</td>
<td>EP: Optional</td>
</tr>
<tr>
<td></td>
<td>EH or CAH: Mandatory</td>
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<tr>
<td>Measure 3 – Case Reporting</td>
<td>EP: Mandatory</td>
</tr>
<tr>
<td></td>
<td>EH or CAH: Mandatory</td>
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<tr>
<td>Measure 4 – Public Health Registry Reporting</td>
<td>EP: Optional</td>
</tr>
<tr>
<td></td>
<td>EH or CAH: Optional</td>
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<tr>
<td>Measure 5 – Clinical Data Registry Reporting</td>
<td>EP: Optional</td>
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<tr>
<td></td>
<td>EH or CAH: Optional</td>
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<tr>
<td>Measure 6 – Electronic Reportable Laboratory Results</td>
<td>EP: Mandatory</td>
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<tr>
<td></td>
<td>EH or CAH: Mandatory</td>
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</tbody>
</table>
This approach retains flexibility for diverse providers to meet MU criteria while also ensuring that important public health needs remain central to Objective 8. Measures 1, 2, and 6 would continue to be required as they were in Stage 2, ensuring continuity of engagement between providers and PHAs. Measure 3 would be added as another core measure because case reporting also provides essential information for public health action to detect and prevent disease. These core public health reporting measures would no longer compete with reporting to PHRs and CDRs, but providers would still be able to pursue registry reporting after meeting or excluding out of the mandatory measures.

Measure 1 - Immunization Registry Reporting
Reference: 80 FR 16764 - 80 FR 16764

Support for Immunization Registry Reporting
JPHIT fully supports the inclusion of bidirectional exchange for immunization registry interoperability in MU 3, as this represents significant value for providers and patients alike. Over half of Immunization Information Systems (IIS) report to CDC that they currently have HL7 2.5.1 query functionality live in production, and this number is increasing rapidly as IIS fully adopt HL7 2.5.1 release 1.5.

Exclusions for Measure 1
As with previous stages of MU, certification tests set a minimal bar for meeting the standard, but should not be considered to represent comprehensive functionality to support nationwide interoperability. JPHIT anticipates that the interpretation of this section will be consistent with previous stages of MU, in that EPs, EHs, and CAHs should not be allowed exemptions based on too conservative of an interpretation of the CEHRT definition and test cases.
Measure 2 - Syndromic Surveillance Reporting
Reference: 80 FR 16764 - 80 FR 16765

Exclusions for Measure 2 - EPs
JPHIT does not support exclusion option (1). Syndromic surveillance accommodates surveillance for “all hazards.” As a result, it is very difficult to provide exclusions by disease or condition. We suggest changing the exclusion (1) to the following wording:
“(1) operates in a jurisdiction that does not accept syndromic surveillance data for the EP’s specialty or practice type – as determined by the public health agency in that jurisdiction (as noted in the central repository).”

Exclusions for Measure 2 - EHs/CAHs
JPHIT does not support exclusion option (1). Option (1) should be amended to clarify that inpatient data are included in syndromic surveillance. Suggested wording is as follows: “(1) Does not have an emergency, urgent care or inpatient setting from which the public health agency wants to receive syndromic surveillance data – as determined by the public health agency in that jurisdiction (as noted in the central repository).”

Measure 3 - Case Reporting
Reference: 80 FR 16765

Support for Case Reporting
We applaud the Centers for Medicare and Medicaid Services (CMS) for putting public health case reporting into the third and final stage of the Meaningful Use (MU) program. We know there are many pressures to limit MU requirements, and are pleased to see CMS advance a rule that enhances the ability of PHAs to protect the public’s health. Poor compliance with laws that require providers to notify public health authorities of patients with reportable health conditions remains a national problem. Hospital reports of ELR and SS data to public health agencies do not satisfy providers’ requirements under these laws. It is therefore crucial that the Meaningful Use programs provide a framework that incentivizes development of EHR functionalities that are necessary for
The case reporting measure (i.e., measure 3) presents a critical policy lever for our nation’s health. As electronic case reporting technologies advance, we anticipate even greater benefits to clinicians and their patients.

There are multiple, national efforts to advance PHA capacities for electronic case reporting for MU Stage 3. These include:

- The Association of State and Territorial Health Officials (ASTHO) works to accelerate advances in case reporting capabilities through the Public Health Community Platform (PHCP), an initiative led by ASTHO and funded by CDC to develop a platform for shared IT services to meet public health needs. ASTHO has convened stakeholders from across the public health enterprise and is developing services to help PHAs be ready to receive case reporting messages for MU Stage 3. More information on the PHCP can be found on www.thephcp.org.

- The Council of State and Territorial Epidemiologist (CSTE) work on the Reportable Conditions Knowledge Management System (RCKMS), another CDC funded project, that is prototyping additional elements of the Case Reporting work flow.

Measure 4—Public Health Registry Reporting
80 FR 16765 - 80 FR 16766

Support for Public Health Registries

JPHIT supports the intent of this measure to provide flexibility for PHAs to encourage reporting to cancer registries and other registries not otherwise specified in Meaningful Use. In the near future, when standards are ready for national use, we hope that this measure will promote and enhance healthcare connectivity with vital records systems.

The inclusion of registries managed by federal agencies, such as the National Healthcare Safety Network and National Health Care Survey, may introduce some complexity in PHA processes for registration of intent to submit data and tracking public health
readiness. JPHIT encourages CMS to clarify the role local, state, or territorial public PHAs may have with regards to reporting to PHRs for MU.

The addition of specific standards for reporting to PHRs is a change from the specialized registry objective in Stage 2 and may pose a problem for states that designated these registries in Stage 2. The lack of a “grandfathering” provision means that reporting to these registries may no longer meet MU, stymieing PHA efforts to build those registries. For example, EPs can presently count reporting to Prescription Drug Monitoring Programs (PDMPs) toward Stage 2’s specialized registry objective (see https://questions.cms.gov/faq.php?id=5005&faqId=11988) and should continue to count such reporting toward Stage 3.

Measure 5 - Clinical Data Registry Reporting
Reference: 80 FR 16766

Clinical data registry definition
JPHIT supports the intension to offer providers greater flexibility in meeting this objective for population health purposes. As discussed above, however, the addition of clinical data registries (CDRs) presents a risk to Stage 1 and 2 gains in public health reporting--especially if a CDR services the health of a limited healthcare practice population.

In addition to our alternative proposal detailed above, JPHIT recommends that CMS revise the CDR definition to ensure that a CDRs data collection practices benefit public and population health work. Specific examples of acceptable CDRs and their respective standards in the final Stage 3 rule would considerably clarify the measure. If sufficient clarity is not possible, then we strongly urge CMS to consider the removal of this measure.

Measure 6 - Electronic Laboratory Result Reporting
Reference: 80 FR 16766
Support for Electronic Laboratory Result Reporting

JPHIT supports the continued inclusion of electronic laboratory result reporting in MU public health measures.