January 13, 2013

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW.
Washington, DC 20201

Re: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic
Health Records

Dear Dr. Mostashari:

On behalf of the Medical Advisory Committee for the Elimination of Tuberculosis (MACET), an
independent group of tuberculosis (TB) experts that advise the Massachusetts' Department of
Health and the State Legislature on matters of TB prevention and control, we write in response to
the request for comments regarding the stage 3 definition of meaningful use of electronic health
records (EHRs) as published in the November 26, 2012 *Federal Register*.

Tuberculosis remains a public health threat and a potentially severe drain on health resources.
There are more than 11 million people in the United States living with TB infection (LTBI),
(Bennett et al. 2008). Additionally, there is in excess of 10,000 active, and therefore deadly and
contagious, cases of TB (CDC, 2011). The larger problem includes endemic TB in most of the
rest of the world, including drug-resistant strains of all types. In today's every shrinking world of
global commerce, study, service and sightseeing, this suggests that shrinking public health
budgets threaten our population's health.

Nevertheless, there are opportunities to strengthen population health efforts, increase efficiency
in the health system, and mitigate some of the public health cuts. Assuring the Meaningful Use
measures and regulations include key public health issues—like TB—is just such an opportunity.
Primary care providers need incentives and assistance in diagnosing and treating TB infection
and TB (e.g. LoBue et al, 2001 and Liu et al. 1998). The public sector can provide this.
Moreover, public health clinicians can aid in identifying key comorbidities of TB (e.g. diabetes
and substance abuse), while primary care providers have access to those most at risk for TB.
Finally, HIT-coding barriers should be minimal, as international health technology experts have
already designed open-source products for TB. Only a fruitful private-public partnering will
result in our achieving TB elimination, thus avoiding unnecessary morbidity, mortality and
expense (e.g. IOM, Ending Neglect, 2000).

In addition to these general comments, MACET also offers the following specific reactions per identification numbers provided by HHS in the request for comments:


## SGRP 104

1. It is unclear what "retire" entails. If it means providers will no longer collect the "retired" demographics, then we suggest not retiring the objective; demographics are essential for public health surveillance, as well as clinical and quality purposes.
2. We further recommend the incentive to record "preferred language" be extended to EPs. "Preferred language," may be a useful proxy for "country of origin," which is related to key high-risk groups for some infectious diseases such as TB. This datum could be linked to clinical decision support mechanisms, and serve as information from the regular workflow that feeds into TB-related quality measures.
   a. CDC. Trends in tuberculosis - United States, 2011. Morbidity and mortality weekly report 2012;61(11):181-185.
   b. Oh, P. "Estimated LTBI burdens by selected TB medical risk population and nativity, California" 2012; see PowerPoint in supporting documents.
   c. Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.
   d. Cain KP, Haley CA, Armstrong LR, Garman KN, Wells CD, Iademarco MF, et al. Tuberculosis among foreign-born persons in the United States: achieving tuberculosis elimination. American Journal of Respiratory and Critical Care Medicine 2007;175(1):75-9.
   e. American Thoracic Society and CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. Am J Respir Crit Care Med 2000;161(4):221S-247.


## SGRP106

MACET agrees with this recommendation. Use of antibiotics for TB beyond protocol length risks toxicity unnecessarily. TB treatment generally involves various types of antibiotics for between 6-30 months, depending on drug-susceptibility. For TB infection, the treatment generally last 9 months. Will this EHR systems' functionality be able to deal with extended-but-not-chronic medication usage?
   a. Mitnick CD, Shin SS, Seung KJ, Rich ML, Atwood SS, Furin JJ, et al. Comprehensive Treatment of Extensively Drug-Resistant Tuberculosis. N Engl J Med 2008;359(6):563-574.
   b. Institute of Medicine. Ending Neglect: The Elimination of Tuberculosis in the United States. Washington, D.C.: National Academy Press; 2000.

**SGRP 113**

This measure could be very useful for population health, especially in the case of potentially epidemic, but low profile, disease such as TB and TB infection. Insulin-dependent diabetes (in those at risk for TB infection), HIV, substance abuse, and those using TNF-inhibitors are at high risk for activation of TB infection. They should be tested and treated. A positive TB skin test or interferon release assay should be a "trigger event" that prompts clinicians to conduct appropriate follow-up and treatment. TB-related clinical decision support interventions (e.g. a pop-up message that suggests testing for TB based on risk factors entered in the medical record) should be included in the preventative care list of options. Treatment for TB infection serves as both primary and secondary prevention and as high quality management of the chronic diseases listed above.

a. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.

b. Horsburgh CR, Rubin EJ. Latent Tuberculosis Infection in the United States. New England Journal of Medicine 2011;364(15):1441-1448.

c. Harries AD, Lin Y, Satyanarayana S, nnroth K, Li L, Wilson N, et al. The looming epidemic of diabetes-associated tuberculosis: learning lessons from HIV-associated tuberculosis. The International Journal of Tuberculosis and Lung Disease 2011;15(11):1436-1445.

d. Oeltmann JE, Kammerer JS, Pevzner ES, Moonan PK. Tuberculosis and Substance Abuse in the United States, 1997-2006. Arch Intern Med 2009;169(2):189-97.

e. Bennett DE, Courval JM, Onorato I, Agerton T, Gibson JD, Lambert L, et al. Prevalence of Tuberculosis Infection in the United States Population: The National Health and Nutrition Examination Survey, 1999-2000. Am J Respir Crit Care Med 2008;177(3):348-355.

f. Jeon CY, Murray MB. Diabetes Mellitus Increases the Risk of Active Tuberculosis: A Systematic Review of 13 Observational Studies. PLoS Medicine 2008;5(7):e152.

g. Taylor Z, Nolan CM, Blumberg HM. Controlling Tuberculosis in the United States. Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. Morbidity and Mortality Weekly Report 2005;54(RR-12):1-81.

h. Oh, P. "Estimated LTBI burdens by selected TB medical risk population and nativity, California" 2012; see PowerPoint in supporting documents.


**SGRP115**

We support this objective as it could aide in surveillance for infectious diseases such as TB and for environmental contaminants. A list of patients with a positive TB test (but no subsequent TB diagnosis or treatment), could prompt public health department outreach to carry out diagnostic studies, and/or offer course of prophylactic treatment. Being able to list all patients with TB or TB infection would also facilitate the calculation of the proposed TB-related quality measures, (see Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The Joint Commission Journal on Quality and Patient Safety 2011;37(7):309-316.).

**SGRP116**

This measure could be adapted to the treatment of TB infection. Six- or 9-month protocols for the treatment of TB infection require monthly follow up visits. The 3-month protocol requires weekly visits. Follow up is essential for treatment completion, and completion is essential for preventing reactivation, out-breaks, and drug-resistant strains. All of which are more expensive than treating TB infection. Furthermore, by increasing treatment for those with TB infection, the US population as a whole benefits, because approximately 80% of TB cases in the US are due to reactivation of TB infection.

   a. Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.
   b. Horsburgh CR, Rubin EJ. Latent Tuberculosis Infection in the United States. New England Journal of Medicine 2011;364(15):1441-1448.
   c. CDC. Session B9, oral presentation: Sterling, PREVENT TB: Results of a 12-Dose, Once-Weekly Treatment of Latent Tuberculosis Infection (LTBI). In; 2011.
   d. Miller TL, McNabb SJN, Hilsenrath P, Pasipanodya J, Weis SE. Personal and Societal Health Quality Lost to Tuberculosis. PLoS ONE 2009;4(4):e5080.
   e. White MC, Gournis E, Kawamura M, Menendez E, Tulsky JP. Effect of directly observed preventive therapy for latent tuberculosis infection in San Francisco. The International Journal of Tuberculosis and Lung Disease 2003;7:30-35.

**SGRP118**

Radiological images are essential for diagnosis and treatment of active TB. However, specialists qualified to interpret these images are rare and growing rarer as expert providers retire. In suspected cases, TB specialists could read digitized films, increasing the chance of a timely TB diagnosis and outbreak termination. Digitized photos of X-rays have been proven effective for the purposes of long-distance diagnosis of TB, (see Szot A, Jacobson FL, Munn S, Jazayeri D, Nardell E, Harrison D, et al. Diagnostic accuracy of chest X-rays acquired using a digital camera for low-cost teleradiology. International Journal of Medical Informatics 2004;73(1):65-73.).

**SGRP122**

This is important for TB and other infectious diseases. For example, the use of IGRAs (blood tests) continue to increase for the purpose of diagnosing TB infection, this function may help improve rapid follow up; this is very important until active TB is ruled out, both in terms of reducing unnecessary treatment and unnecessary costs.

   a. Fraser HS, Thomas D, Tomaylla J, Garcia N, LeccaL, Murray M, Becerra MC. Adaptation of a web-based, open source electronic medical record system platform to support a large study of tuberculosis epidemiology. BMC Med Inform Decis Mak. 2012 Nov7; 12(1):125.

    b.  Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.

    c.  Blaya J, Shin S, Yagui M, Yale G, Suarez C, Asencios L, et al. A web-based laboratory information system to improve quality of care of tuberculosis patients in Peru: functional requirements, implementation and usage statistics. BMC Medical Informatics and Decision Making 2007;7(1):33.

    d.  Miller TL, Reading JA, Hilsenrath P, Weis SE. What are the costs of suspected but not reported tuberculosis? Annals of epidemiology 2006;16(10):777-81.

## SGRP206

Culturally competent patient education is critical for successful treatment of infectious diseases, including TB infection and TB. TB is endemic in the majority of the world, therefore most US residents born abroad will have increased risk for TB infection. We support the additional language support and suggest that more action in this area is needed.

    a.  CDC. Trends in tuberculosis - United States, 2011. Morbidity and mortality weekly report 2012;61(11):181-185.

    b.  WHO. Multidrug and extensively drug-resistant TB (M/XDR-TB): 2010 Global report on surveillance and response. In. Geneva, Switzerland; 2010

    c.  Munro SA, Lewin SA, Smith HJ, Engel ME, Fretheim A, Volmink J. Patient Adherence to Tuberculosis Treatment: A Systematic Review of Qualitative Research. PLoS Med 2007;4(7):e238.

## SGRP305

Does this item address referral loops between primary care providers and public health providers? For example, one community-based TB prevention model refers people with TB infection back to their community health center (after TB infection is confirmed and active TB is ruled out). During this process, public health providers are identifying other high-priority comorbidities (e.g. diabetes and substance abuse) and the primary care providers are referring complex TB cases back to the public health providers.

    a.  Oh, P. "Estimated LTBI burdens by selected TB medical risk population and nativity, California" 2012; see PowerPoint in supporting documents.

    b.  Privett, T. "Collaborating with FQHCs: The New Jersey Experience." 2011; see PowerPoint in supporting documents.

## SGRP401A

It is important for a provider to know if a patient received the BCG vaccine, a globally used—with the exception of the US—vaccine for the prevention of two types of childhood TB. The diagnosis of TB later in life, when using the TST skin test, will differ depending on BCG history.

    a.  Horsburgh CR, Feldman S, Ridzon R. Practice guidelines for the treatment of tuberculosis. Clinical infectious diseases 2000;31(3):633-9.

b. American Thoracic Society and CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. Am J Respir Crit Care Med 2000;161(4):221S-247.

## SGRP402A

TB is a reportable disease in all states due to the potential for massive negative externalities; TB infection is a reportable disease in a handful of states. Are all eligible EHRs capable of reporting these two diseases to public health agencies? If not, additional work with vendors may be required. It is feasible and likely low-cost to do so, because there are many TB-related open-source software programs already developed. If the capacity exists, we strongly support this objective and measure due to extreme negative impact on lives and the economy should we suffer a TB outbreak.

a. Fraser HS, Thomas D, Tomaylla J, Garcia N, LeccaL, Murray M, Becerra MC. Adaptation of a web-based, open source electronic medical record system platform to support a large study of tuberculosis epidemiology. BMC Med Inform Decis Mak. 2012 Nov7; 12(1):125.

b. Blaya JA, Cohen T, Rodriguez P, Kim J, Fraser HSF. PDAs to collect tuberculosis bacteriology data in Peru reduce delays, errors, workload, and are acceptable to users: Cluster randomized controlled trial. Int J Infect Dis. 2009 May; 13(3): 410-8.

c. Miller TL, McNabb SJN, Hilsenrath P, Pasipanodya J, Weis SE. Personal and Societal Health Quality Lost to Tuberculosis. PLoS ONE 2009;4(4):e5080.

d. Freudenberg N, Fahs M, Galea S, Greenberg A. The Impact of New York City's 1975 Fiscal Crisis on the Tuberculosis, HIV, and Homicide Syndemic. Am J Public Health 2006;96(3):424-434.

e. Fraser HSF, Blaya J, Choi S, Bonilla C, Jazayeri D. Evaluating the impact and costs of deploying an electronic medical record system to support TB treatment in Peru. In: AMIA Annual Symposium proceedings; 2006. p. 264-8.

f. Seebregts CJ, Mamlin BW, Biondich PG, Fraser HSP, Wolfe BA, Jazayeri DG, Allen C, Miranda J, Baker E, Musinguzi N, Kayiwa D, Fourie C, Lesh N, Kanter A, Yiannoutsos C, Bailey C. The OpenMRS Implementers Network. Int J Med Inform. 2009 Nov;78(11):711-20.

g. Jack W. The public economics of tuberculosis control. Health Policy 2001;57(2):79-96.

## SGRP402B

Clinicians sometimes fail to send documentation on reportable diseases, especially ones like TB infection. Having automatic, electronic data sent directly to health departments will help ease the burden on clinicians and improve population health. Not all risk factors for infectious disease case reports are recorded in EHRs, but the existing ones will expedite case finding and follow up, and potentially saving money because of reduced time to case resolution (see for example,

**SGRP405**

Clinicians sometimes fail to report infectious diseases or suspected infectious diseases at the point of diagnosis even when such reporting is legally required. This situation is further exacerbated for those conditions requiring longer-term disease management, such TB, TB infection, HIV, hepatitis B, hepatitis C and syphilis. Systems such as the MDPHNet Electronic Support for Public Health (ESP) are able to automatically report key longitudinal data for these select, notifiable diseases automatically to the health department. For example, these data may include a change in medication of a patient with active tuberculosis or evaluation of treatment effectiveness against viral load in individuals infected with HCV. This is also relevant to a contact investigation and in prevention of pediatric cases. In addition to supporting improved clinical outcomes, these registries have the potential to support public health policy development. (See Klompas M, Lazarus R, McVetta J, Eggleston M, Haney G, Kruskal B, Yih WK, Daly P, Oppedisano P, Beagan B, Lee M, Kirby C, Heisey-Grove D, DeMaria A, Platt R. Integrating clinical practice and public health surveillance using electronic medical record systems. Am J Public Health 2012; 42(6S2):S154-S162.*).*

- Stage 3 Proposed Objective: MACET recommends that this objective requires the capability to identify and report selected cases of notifiable infectious diseases to a public health agency, except where prohibited, and in accordance with applicable law and practice. Platforms such as MDPHNet ESP or standardized document architectures such as CDA should be recommended.
- Stage 3 Proposed Measure:  Successful ongoing submission of specific case or suspected case information from Certified EHR technology to a public health agency

**QMWG01**

Increasing screening and treatment for TB infection will decrease healthcare costs. Treatment of TB infection reduces incidence of active disease. Active disease is very expensive and entails outbreak investigations, sometimes very costly medication, and inpatient isolation. This isolation is sometimes involuntary and requires police and other public safety resources. Medical personnel are often infected as well.

a. Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.
b. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.
c. Miller TL, McNabb SJN, Hilsenrath P, Pasipanodya J, Weis SE. Personal and Societal Health Quality Lost to Tuberculosis. PLoS ONE 2009;4(4):e5080.
d. Rajbhandary SS, Marks SM, Bock NN. Costs of patients hospitalized for multidrug-resistant tuberculosis. Int J Tuberc Lung Dis 2004;8(8):1012-6.

**QMWG02**

All EHR systems should have the capability of adding one or more TB-related measure since, especially, with the continued emergence of drug-resistant strains, TB remains a threat to population health.

a. "TB's Global Resurgence Amplifies U.S. Risk - WSJ.com"
http://online.wsj.com/article_email/SB10001424127887324296...

b. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.

c. Bennett DE, Courval JM, Onorato I, Agerton T, Gibson JD, Lambert L, et al. Prevalence of Tuberculosis Infection in the United States Population: The National Health and Nutrition Examination Survey, 1999-2000. Am J Respir Crit Care Med 2008;177(3):348-355.

d. Freudenberg N, Fahs M, Galea S, Greenberg A. The Impact of New York City's 1975 Fiscal Crisis on the Tuberculosis, HIV, and Homicide Syndemic. Am J Public Health 2006;96(3):424-434.

e. Institute of Medicine. Ending Neglect: The Elimination of Tuberculosis in the United States. Washington, D.C.: National Academy Press; 2000.


**QMWG04**

Again, one or more TB measures should be available for all menus since it is such a vital population health issue, but only targeted testing is cost-effective.

a. Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.

b. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.

c. American Thoracic Society and CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. Am J Respir Crit Care Med 2000;161(4):221S-247.


**QMWG10**

This sounds like the more useful approach. For example, another HIV process measure should be "tested for TB"; there could also be an optional, complete suite of TB-related measures including the outcome of necessity: treatment completion.

a. CDC. Mortality Among Patients With Tuberculosis and Associations With HIV Status--United States, 1993-2008. JAMA: The Journal of the American Medical Association 2011;305(10):993-995.

b. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.

**QMWG16**

"Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease" and "Making care safer by reducing harm caused in the delivery of care" should be prioritized. TB-related measures will address the former in that TB activities improve the prevention and treatment of a comorbid condition for people with top mortality concerns (e.g. diabetes, HIV, etc). We also address reduction of harm in the cases where TB is screened and found, but would otherwise have been misdiagnosed as pneumonia, which frequently leads to recruitment of drug resistance. (See for example, Bernardo J, Yew W. How Are We Creating Fluoroquinolone-resistant Tuberculosis? Am J Respir Crit Care Med 2009;180(4):288-289.)

**QMWG17**

We submit a family of TB-related measures as exemplar measures. If only some are to be chosen, we recommend those related to HIV, foreign-born and TNF-inhibitors as the top three measures to consider.

    a. Tschampl C, Bernardo J, Garvey T, Garnick D. The need for performance measures on testing for latent tuberculosis infection in primary care. The joint commission journal on quality and patient safety 2011;37(7):309-316.

    b. Linas B, Wong A, Freedberg K, Horsburgh CR. Priorities for screening and treatment of latent tuberculosis infection in the United States. American journal of respiratory and critical care medicine 2011;184(5):590-601.

**QMWG18**

We believe an optional innovation track would be tremendously helpful as community health centers explore new ways to seek out and treat TB infection. In addition, if TB-related measures are not immediately included in the MU CQM pipeline, it would be good to share them so that other providers could benefit from using them under this innovation option.

As strong supporters of HIT, we thank HHS for the opportunity to offer these critical recommendations and detailed reactions. We cannot emphasize enough the need to require EHRs to have the capacity to collect and code data relevant to TB, TB infection and related measures so that those providers serving populations at high-risk can better serve the health of their patient panels. We are happy to make ourselves available for any questions you might have or clarifications you might need.

Sincerely,
Cynthia Tschampl, PhD Candidate & Tom Garvey, MD, JD
Co-Chairs, Government Relations Committee
Medical Advisory Committee for the Elimination of Tuberculosis (MACET)