

January 27, 2017

Lauren Peel Contract Specialist Center for Disease Control and Prevention U.S. Department of Health and Human Services 2920 Brandywine Road, Room 3000 Atlanta, Georgia 30341-4146

Re: CDC Request for Information – Clinical Decision Support [2017-RFI-CDS-0001]

Dear Ms. Peel,

On behalf of the American College of Physicians (ACP), I am writing to share our comments on Centers for Disease Control and Prevention (CDC) Request for Information (RFI) on Clinical Decision Support (CDS). ACP works to provide our physician members with evidence-based content that will keep them updated on best practices and current guidelines for inpatient and outpatient care. Our tools include:

- Annals of Internal Medicine: the most widely-cited peer-reviewed medical journals in the world
- Clinical Guidelines: ACP's highly respected best practices and evidence-based guidelines updated for inpatient and outpatient care
- *DynaMed Plus*[®]: Through ACP's collaboration with EBSCO Health, ACP members have access to the most current, evidence-based clinical decision support tool.

ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 148,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College appreciates the opportunity to provide information to the CDC on CDS from the physician perspective. The CDC serves as a content producer of many guidelines, recommendations, and best practices that are translated into CDS tools and implemented within clinical workflows. The CDC and clinicians share the goal of improving people's health,

which would benefit from better coordination between publication of the evidence-based content and translation into effective CDS tools. It is extremely important when developing these tools to consider the end user in the scenario – the clinician – and how this information can best be used in the clinical care setting. Without considering how this information is being accessed and used by physicians, additional tools can become a hindrance rather than an enhancement.

To help inform approaches to CDS development that impacts public health interests, ACP provides the below feedback to the proposed questions:

1. CDC requests that respondents confirm the completeness and correctness of each of the lists above or provide any missing potential focus areas or stakeholder groups in the CDS development and implementation process.

As stated above, the College applauds the CDC for the thorough list of respondents including and soliciting comments from Clinicians, Hospitals/Hospital Systems. These respondents are the end users. They and their patients benefit directly from CDS tools in the clinical care setting.

2. How can public health add the most value to CDS development and implementation? What role should CDC play? Please describe these opportunities for added value and include examples, where possible, to illustrate (e.g., if there are specific ways CDC could add value in certain domains, such as guidelines development or translation, standards development, convening stakeholders, etc.).

In general and where possible, authors should keep the end result and their audiences in mind with best practice guidelines. Where a clinician audience might appreciate nuance in a narrative description, the audience of electronic health records (EHRs) will not. Best practice guidance for EHRs should attempt to be limited to rules that can readily be implemented and do not require clinical judgment with each step. Public health guidance, CDS alerts, and electronic specifications for clinical quality measures (eCQMs) should be harmonized such that doing the right thing does not count as the wrong thing in the eyes of the Centers for Medicare and Medicaid Services (CMS) and other payers.

The history of CDC involvement in health information technology (health IT) standards development has been a series of attempts by different offices within CDC to develop uncoordinated standards for specific use cases using various incompatible approaches and different standards development organizations (SDOs). The results have been incompatible standards that are extremely difficult to implement. Attempts by standards experts to steer CDC groups into more productive directions have been unsuccessful. CDC should not attempt to lead development of standards. Instead, CDC should cooperate with existing SDOs to use existing clinical standards and to minimize the variability that is permitted.

3. What are some examples of CDS currently being used in EHRs with potential public health implications (e.g., population-based screening, outbreak-specific screening, etc.)? Please describe each tool and how it is used in clinical settings.

There are several examples of CDS use in EHRs with potential public health implications:

- <u>Practice Innovation Institute</u> Practices enrolled in the Practice Innovation Institute (a Transforming Clinical Practice Initiative [TCPI]) are part of a partnership with the state Health information Exchange (HIE). Hospitals and enrolled practices are working on a program to alert the enrolled practices when a high-risk patient makes contact with any health entity. Work is being done on triggers based on gaps in care and certain diagnoses such as asthma, diabetes, etc.
- <u>Cancer screening</u> CDS uses "if /then" statements that base database searches for last result (if any) on age, sex, and other factors. Some CDS show prior results within the alert; and some also allow a series of actions (i.e., done by another clinician, order, defer, decline) with a single click. Further, depending on the setting and availability of standing orders, some CDS systems are presented to the patient as part of a pre-visit process, with the ability to place the standing order by the medical assistant (MA) or nurse. Some primary care physicians (PCPs) use this for breast, cervical, colorectal, and prostate cancer screening. Even before physicians started paying attention to eCQMs for cancer screening, some physicians decided to do this regardless of whether the patient has another doctor (such as a gynecologist) order the tests and review the results. It is the standard of care for the PCP to know that the patient is up-to-date with cancer screenings, even where done by another physician.
- <u>Vaccinations</u> CDS uses "if /then" statements that base database searches for last result (if any) on age, sex, and other factors. Some CDS show prior results within the alert; and some also allow a series of actions (i.e., done by another clinician, order, defer, decline) with a single click. Further, depending on the setting and availability of standing orders, some CDS systems are presented to the patient as part of a pre-visit process, with the ability to place the standing order by the MA or nurse.
- <u>Screening for conditions</u> Some physicians currently use CDS to screen for HIV, Hepatitis C, and diabetes. CDS works similarly to what is described above for cancer and vaccination screening. It is sometimes more difficult when screening conditions are sometimes not amenable to information that is, or expected to be, in the EHR. For example, Hepatitis C screening for a baby boomer is "once and done" except for patients with illnesses or lifestyle practices that might put them at risk for exposure; and then it is more frequent.
- 4. How is information tailored in EHRs based on public health knowledge (e.g., focused on a particular geographic location or patient population, based on public health alerts received vie email or through electronic health records (EHRs), etc.)? Please include any

specific challenges or barriers in being able to apply public health information in order to tailor the delivery of care.

Most CDS in EHRs is based on generic knowledge or CDC best practice guidelines, and not on geographic or isolated population updates. While what is suggested may seem reasonable, unless the CDS programming was done by the vendor, with appropriate post-modification testing, it would require end-users with appropriate privileging to be able to modify code and do appropriate testing. This is something easy enough for large health systems with Chief Medical Informatics Officers (CMIOs) and/or informatics support, but not feasible for solo or small practices.

One of the biggest successes has been in diagnosing obesity and screening for chronic diseases. The EHR provides the automated trigger for body mass index (BMI) and with training physicians are able to use templates and referrals for life-style modifications and coaching. Specific barriers include time and lack of significant reimbursement (particularly for billing codes that involve behavior modification). Currently the EHRs do not have easy workflows to incorporate public health alerts. For example, a robust patient portal incorporated into the EHR could trigger Zika or Ebola based on a travel questionnaire.

While doctors will always aim to do whatever is in the best interest of the patient, with the increased importance of value-based payment, doctors may find themselves recommending testing/screening or treatment that is not covered by the patient's insurance and may also be at odds with existing eCQMs. The best approach would be to have recommendations, insurance coverage, and eCQMs concurrently align; however, this likely is not a feasible approach. Another method, at least for eCQMs, is to harmonize their build as much as possible so the additional numerator of "medical reason" always exists, and thus is available for ready use prior to the eCQM being updated.

5. Have you previously worked with public health agencies around CDS development (this could include anything from "translating" guidelines into structured decision algorithms, to defining standards, to developing or piloting CDS tools)? If so, please describe that experience.

No Comment

6. What are the challenges you face in the CDS development and implementation process? How do those challenges affect you? How would you ameliorate or eliminate those challenges?

Denominator and numerator definitions are sometimes too vague to be useful and the process of building the rules to support the denominator and numerator involves interpretation. If best practice guidance were developed with the end-user in mind and without such vague terms requiring clinical judgment, these challenges could be reduced. 7. Who should develop and maintain public health CDS tools? How can proof of concept CDS pilots be scaled faster? What resources are needed to achieve this scalability?

The CDC should develop and maintain public health CDS tools. Proof of concept could be accelerated with a funded pilot from CDC and participation by the largest EHR companies.

8. How might the exchange of data and knowledge between EHRs and public health agencies be improved? Please provide examples of how this exchange currently occurs (whether unidirectional or bidirectional) and identify specific challenges or barriers you have encountered.

Medical practices and hospitals are required to engage with all of the national public health authorities as well as those in their service area, which often includes several states and other jurisdictions. Unless public authorities are compelled to coordinate and simplify reporting requirements, physicians and other clinicians are guaranteed undue complexity and expense.

A major concern with almost all reporting requirements is that they are one-way. Practices and hospitals must collect and supply data to target agencies, but there is no requirement at all for these agencies to report back to the health systems. The definition of "active engagement" must be expanded to require that all public health data exchanges be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than improvements in health. Patients and their doctors will benefit greatly from requirements that public health agencies report back in a timely manner and with meaningful data, such as intelligence about what is happening in the community.

Immunization and other public health registries still have unique and nonstandard requirements. It is not sufficient for all public health agencies to agree to use the same data standards. Immunization information is not always bidirectional and to make immunization information system (ISS) information work for doctors (and patients) it needs to be. They must all also agree to use identical reporting process requirements. EHRs must not be required to accommodate variability in public health requirements. There is a responsibility for all of public health to update their systems to a single set of data and reporting standards. Serious illness and bioterror threats are primarily via text, email, or print. Having a curated and secure bulletin to EHRs could better serve the public's interest.

There is an expectation that public health reporting will require duplicative documentation into an electronic form, rather than the reporting system accepting commonly used formats such as the export of a summary of care document (SoCD). There cannot be a requirement that practices and hospitals implement a separate interface to each reporting entity. Significant costs and effort could be saved by requiring that reporting entities work together to simplify reporting burden. This could be accomplished with the development of a standard Application Programming Interface (API) for all public health, quality, and registry reporting. To summarize, it is incumbent on CDC to develop and enforce a common data standard, a common reporting process, and a single portal to be used for all public health reporting. In addition, all reporting must be meaningfully bidirectional.

9. How could clinical data and EHRs be more effectively used for public health purposes? How could health information exchanges (HIEs) play a role?

EHRs should be configurable to share data seamlessly with public entities. For physicians, that would mean a more effective means/less of a burden to report and no duplicative reporting where different interfaces have to be created and managed for each use.

The burden should be on public health authorities to present health care delivery organizations with a single target for all data reporting. This could be delivered as a single national portal/registry or local/regional entities such as HIEs that all support common data and process standards for all reporting by providers and data query/collection by public health authorities.

Public health authorities need to rethink their data "needs." When they require data from practices and hospitals, they usually require that the data elements be defined, structured, and formatted differently from the way the data are collected during the delivery of clinical care. This means that the reporting clinicians have to manipulate the data in ways that decrease the accuracy and value of the data elements.

Public health authorities believe that they are receiving data that match their intentions, but this is often not the case. The data that public health authorities typically receive may be so distorted by the conversion or double entry processes that they will not serve the purposes of public health. Rather than forcing data collectors to manually enter duplicative data to match public health specifications, public health should redesign its processes to accept and use the clinical data in the form and structure that they are routinely collected by clinicians during the care delivery processes

10. Where are the opportunities for public health surveillance data to inform clinical decisions? What are the barriers? How would you implement an effective bidirectional feedback loop between a clinical setting and public health agency or CDC?

Public health authorities have an obligation to provide practices and hospitals with timely and actionable results from the data they collect. At present, there are many research projects underway attempting to develop ways to automate the implementation of CDS in EHRs. It appears too early for CDC or anyone else to pick a solution, or even a direction, from what is presently available. CDC's current focus should be on identifying and evaluating current approaches under development. Some other opportunities around public health surveillance data to inform clinical decisions are:

• <u>Heat maps</u> (zip codes of high poverty that impact the social determinants of health) – There is an opportunity to use heat maps to trigger reminders and tools for referrals. In states that have a HIE that is robust; there is a high potential for incorporating the elements of public health surveillance to help inform clinical decisions.

- <u>Infectious diseases alerts</u> Infectious diseases such as influenza, measles, etc., could be areas where the public health surveillance can easily be included in the EHRs, based on vaccination history.
- <u>Environmental related issues/diseases</u> For example, rising numbers of children with high lead levels identified by zip codes could potentially trigger a warning system for enhanced surveillance that could have potentially prevented the catastrophe in Flint, MI. Other environmental issues such as chronic obstructive pulmonary disease (COPD) and asthma have the opportunity to be better cared for by incorporating environmental data (e.g., via national weather data, pollen and dust levels, etc.) to screen for potential worsening in patients who have an advanced/severe disease.

The barriers to these propositions include costs for interface building (particularly to small practices) and the ability to tie into the EHR via interfaces. In addition the human element (i.e., ease of use for the physicians and their team) is the biggest factor that will determine success of these initiatives. Physicians and their teams are inundated by the reporting requirements and any additional tasks are usually met with a fierce opposition

Not all clinicians subscribe to or read CDC bulletins. Most/all EHRs have the ability to display key messages upon log-in, either once or repeatedly, and this feature is typically used to announce scheduled downtimes and upgrades. It could be an easy first step in at least getting the word out to clinicians about key outbreaks or bioterror threats. This can be informational only, without necessarily being developed as a CDS alert. Barriers would include over-alerting, alert prioritization, shelf life, and mischief or misinformation from hackers. Thus, the ability for the CDC to create banner headlines, such as "WARNING – Ebola now seen in travelers from Liberia," with the ability to click through for more information, latest updates, etc., could be very helpful. This could be similar to an Emergency Broadcast System for health care professionals.

To be effective, the headline alert system needs to be managed carefully by a select group, where not every announcement or update becomes a headline. Just as we have seen with EHRs and problem list maintenance, it is easy to add problems, and more difficult to edit and/or remove them. A headline alert system is useless if there are too many and out-of-date alerts. Further, it needs to be "hack-resistant." Where there is more time, a CDC subgroup could create informational alerts packaged as CDS alerts, ready for consumption by EHRs.

The feedback loop is also important. Feedback is most effective when it does not always require duplicative information entry into a CDC reporting form. For example, the ability to take a headline or a CDS alert, click a "FEEDBACK" button, and enter a brief comment could be very helpful. Similarly, the ability to securely attach results or findings or even a note could make feedback submission easy and allow for more detailed comments, should they be necessary.

11. Should there be a different approach for CDS in emergency scenarios versus less urgent scenarios (e.g., in outbreak responses such as Zika or Ebola vs. in chronic conditions

such as heart disease or stroke)? Why or why not? Please describe in your response how the scenarios should be approached the same or differently.

In the case of emergent scenarios, where there is no time to create logic rules and go through testing pre- and post-implementation, simply delivering curated alerts via a secure channel could be exceedingly useful.

We commend CDC on their work to improve upon CDS tools through evidence-based guidelines, recommendations, and best practices that ultimately help achieve the improvement of people's health. We look forward to continuing our work with the CDC and ensuring the physician's voice is heard in the development of tools that affect their practice. Should you have any questions, please contact Blair Hedgepeth, Senior Associate for Health IT Policy at <u>bhedgepeth@acponline.org</u>

Sincerely,

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Peter Basch, MD, MACP Chair, Medical Informatics Committee American College of Physicians