October 17, 2018

Dr. Don Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
200 Independence Ave SW
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the AMGA, we appreciate the opportunity to comment on the Office of the National Coordinator's (ONC's) "Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program."

Founded in 1950, AMGA represents more than 450 multi-specialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one-in-three Americans. Our member medical groups work diligently to provide innovative, high quality patient-centered medical care in a spending efficient manner. Many of our medical groups currently participate in the Medicare Shared Savings Program (MSSP) or the Accountable Care Organization (ACO), in the Track 1+ and Next Generation ACO demonstrations, the Comprehensive Primary Care + model, as well as other related Medicare demonstrations. AMGA, therefore, has a strong interest in improving population health, care quality and reducing Medicare spending growth via the use of ever-improving Electronic Health Record (EHR) functionality.

AMGA members were early adopters of EHRs and e-prescribing. Most of our members are now on their second or third version of their EHR, so they are keenly aware of the value that the EHR reporting program will provide. We appreciate the breadth of ONC's work to bring this to life, and we agree it is important to address each of the identified topic areas. That said, we will limit our comments to addressing the interoperability category. Specifically, our comments relate to the use of next-generation predictive models in shared decision-making at the point of care.

AMGA's advocacy has long focused on aligning payment incentives with population health (our "Value Agenda"), and AMGA's educational and shared learning programs focus on helping members redesign their delivery systems to efficiently manage population health.

We are working with a number of our member organizations in a learning collaborative that we conduct in partnership with Optum Analytics and OptumLabs, examining "population dynamics."

Through this partnership, we have access to longitudinal EHR data on more than 30 million people.

As background, we will provide two examples of predictive models that are important for people with diabetes and their providers. Type 2 diabetes affects approximately 28 million Americans, and managing blood sugar levels is crucial in preventing serious complications. Yet most healthcare organizations consistently struggle to increase the proportion of patients in glycemic control. Why the slow progress? When we examine longitudinal data, it becomes clear that it's like trying to fill up a leaky bucket.

From one year to the next, most organizations are able to bring about 9% of their total population with Type 2 diabetes from out-of-control to in-control. But this is offset by about 8% of the population who slip from in-control to out-of-control, so the net improvement is only an additional 1% of the population in control. Of course, many of the people who move from in-control to out-of-control and vice-versa are close to the threshold, so small variations will change their status. But about 5% of those who appear "safe," i.e., in control and well below the threshold, will slip out of control over the next 12–15 months.

We have developed a predictive model to identify patients who appear "safe" but are likely to slip out of control. These patients would benefit from some extra attention during their office visit, perhaps also having a care coordinator reach out to them periodically, and maybe bringing them back earlier than usual for a follow-up visit. But for that to happen, the results of the predictive model must be available to the provider at the point of care, while he or she is seeing the patient.

These predictive models are complex calculations, involving many parameters. In fact, different models may be needed to get the best predictive power for patients at different stages of their disease, or different models depending on what data elements are available in the EHR for a given patient.

Here's one more example that leads directly to our comment. Working with the Predictive Analytics and Comparative Effectiveness (PACE) Center at Tufts Medical Center, we received a small Patient-Centered Outcomes Research Institute (PCORI) grant to implement a predictive model for people with pre-diabetes. This model was developed by Tufts by reanalyzing data from the Diabetes Prevention Program (DPP) study.[1] It identifies one-quarter of people with prediabetes who are likely to gain twice the average benefit from the DPP intensive lifestyle intervention, which CDC is promoting and which CMS is now covering for Medicare beneficiaries. The model also identifies one-quarter of patients who will gain *triple* the average benefit from taking metformin, the other intervention considered in DPP Study. And it identifies one-quarter of people with pre-diabetes who will gain essentially no benefit from these interventions.[2,3]

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[1] https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp

[2] Sussman JB, Kent DM, Nelson JP, Hayward RA. Improving diabetes prevention with benefit-based tailored treatment: Risk-based reanalysis of Diabetes Prevention Program. *BMJ* 350 (February 2015): h454.

[3] https://www.pcori.org/research-in-action/moving-beyond-averages

This multi-variable model is a much better predictor than any individual clinical parameter and thus very valuable for shared decision-making with a person who has been found to have pre-diabetes. But some provider organizations are already so overwhelmed by the number of people with pre-diabetes, they aren't even prioritizing practice-based screening. Yet screening for diabetes is critically important for population health, as one in four people who have Type 2 diabetes are unware; and, it is nearly twice that proportion among Asian and Hispanic Americans.[4]

The value of this predictive model for shared decision-making has been confirmed by early qualitative results from its use in two AMGA member organizations, as part of our PCORI-funded study.

We cite these two examples to illustrate the **compelling practical value of making the results of multi-variable predictive models available to providers and patients at the point of care, to support shared decision-making.**

In the PCORI project, we have learned that it can be very difficult for organizations to embed complex mathematical models like this in their EHRs (it would be even more challenging to implement models based on machine learning techniques). One organization found they would need to license additional software from their EHR vendor, at a quoted fee well over $100,000, to access data already stored in their EHR, in a way that they could use in these models.

That organization recommended we consider a different approach, based on evolving standards, that would be much more scalable to other organizations: build a SMART app (https://smarthealthit.org) that can be hosted in the cloud, using the Fast Healthcare Interoperability Resources (FHIR) standard (https://www.hl7.org/fhir/overview.html) to obtain patient data via this mechanism, which a growing number of EHR vendors are committing to expose for this purpose (Argonaut project, http://argonautwiki.hl7.org/index.php?title=Main_Page).

In addition to obtaining the necessary data and performing the calculation, there is also the question of recognizing when the model is needed and presenting the results in the clinical workflow. Fortunately, there is also an evolving standard for that, CDS Hooks (https://cds-hooks.org). This is less mature than the other standards, but it's the final element needed for wide, standards-based deployment of cloud-hosted "SMART on FHIR" apps. With these standards, it is now realistic to anticipate this as a practical solution to real challenges faced by provider organizations in managing population health, not just a theoretical possibility.

This approach will allow the industry to create more complex models, including conditional logic, which are far better predictors than the relatively simple equations that it is practical to embed in an EHR (even if you have the extra-cost license required to obtain an individual patient's data for the calculation). Moreover, for health care as a whole, it means that the software development and testing can be done once, and maintenance can be carried out in one place, as better predictive models are developed.

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[4] Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and trends in diabetes among adults in the United States, 1988–2012. *JAMA* 2015; 314: 1021–1029.

This is a tremendously valuable aspect of interoperability. It is important that EHR vendors have every incentive to expose all the data elements available for a specific patient, so the data can be retrieved by SMART apps, to accept the results of these models, and to present them in the clinical workflow.

It is also important that EHR vendors do not come to view this as a potential "click charge" revenue stream. Provider organizations have paid, often handsomely, for their EHR software, and they have worked to create and curate the patient data that are stored in the EHR. Fundamental to the concept of interoperability is that the data should be freely available, with appropriate security, for uses such as this, both at the individual patient level, for shared decision-making, and also at the population level, to allow refinement of the predictive models and the clinical decision support logic.

The EHR reporting envisioned by the 21st Century Cures Act should provide a way for EHR vendors to demonstrate their commitment to openness and interoperability by confirming their full compliance with these evolving standards for exposing patient data and receiving and presenting the results of these models in the clinical workflow. **EHR reporting should also enable EHR vendors to demonstrate their willingness to impose no more than a nominal charge for their use** (but specified, to avoid ambiguity about the interpretation of "nominal").

Thank you for the opportunity to comment. If you have questions, please do not hesitate to contact John Cuddeback, MD, PhD, AMGA's Chief Medical Informatics Officer, jcuddeback@amga.org, 703-838-0033.

Sincerely,

Jerry Penso, M.D., M.B.A.
President and Chief Executive Officer