Interoperability Standards Priorities (ISP) Task Force

Transcript
June 25, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Role
Kensaku Kawamoto (Co-Chair)	University of Utah Health	Co-Chair
Steven Lane (Co-Chair)	Sutter Health	Co-Chair
Andrew Truscott	Accenture	Member
Anil Jain	IBM Watson Health	Member
Arien Malec	Change Healthcare	Member
Clement McDonald	National Library of Medicine	Member
Cynthia Fisher	WaterRev, LLC	Member
David McCallie	Individual	Member
Edward Juhn	Blue Shield of California	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Google	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Ricky Bloomfield	Apple	Member
Sasha TerMaat	Epic	Member
Scott Weingarten	Cedars-Sinai Health System	Member
Tamer Fakhouri	Livongo Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Tina Esposito	Advocate Aurora Health	Member
Valerie Grey	New York eHealth Collaborative	Member
Victor Lee	Clinical Architecture	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

GUEST SPEAKERS

Name	Organization
Noel Eldridge	AHRQ
Erin Grace	AHRQ
Zach Hettinger	Medstar Health
Joella Roland	Center for Medicare & Medicaid Services (CMS)

Operator
All lines are now bridged.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. Good morning, everyone and welcome to the ISP task force meeting. Today, we're going to have continued discussion with guest speakers on standards and specifications around medication and pharmacy data. So, let me begin by taking roll so we can officially start. Ken is on vacation. Steven Lane.

Steven Lane - Sutter Health - Co-Chair
I am here. Good morning, everyone.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Anil Jain.

Anil Jain - IBM Watson Health - Member
I'm here, good morning.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning. Arien Malec.

Arien Malec - Change Healthcare - Member
Good morning.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning. Andy is on vacation. Clem McDonald.

Clement McDonald - National Library of Medicine - Member
Here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Cynthia Fisher. David McCallie.

David McCallie - Individual - Public Member
Here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer

Clem McDonald.

Clement McDonald - National Library of Medicine - Member
Here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. Edward Juhn. Terry O'Malley. Leslie Lenert. Jack Po. Raj Ratwani. Ram Sriram.

Ram Sriram - National Institute of Standards and Technology- Member
Present.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Ricky Bloomfield.

Ricky Bloomfield - Apple - Member
Good morning. I'm here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning. Sasha TerMaat. Scott Weingarten. Sheryl Turney. Tamer Fakhouri.

Tamer Fakhouri - Livongo Health - Member
Good morning. I'm here.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning. Tina Esposito. Valerie Grey. And Victor Lee. Okay. So, Steven, I'll hand it over to you. Thank you.

Steven Lane - Sutter Health - Co-Chair
Thank you so much and welcome, everyone. I do see Sasha has shown up on the Adobe Connect. So, I imagine we'll have some other folks joining us as we go along. So, welcome, everyone to the June 25 meeting of ONC's interoperability standards priorities task force. As Cassandra said, we are continuing our exploration of the domain of medication and pharmacy data. Can we go on to the next slide? I wanted to remind everyone both our task force members and our visitors of the charge of our task force, which is to make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses. So, you all recall readily that we've been working through some of those uses and currently are discussing data related to medications and pharmacy.

We have been through a number of areas. And today, we are going to be focusing primarily

on the area of adverse medication events. This is an area that was recommended really by folks who are working in the area of patient safety and how EHRs have had patient safety. And as we've discussed, we saw this as one of those areas where it would be helpful perhaps to explore both the existing standards and the opportunities related to this domain. So, we've been successful in reaching out to a number of folks who work in this area and are really looking forward to getting their input.

Again, for the presenters, our specific charge is to really understand the existing standards and implementation specifications that are in place and then, to understand where there may be opportunities to either advance the standards or advance how they are being implemented in the real world to see if we can improve the exchange of data, in this case, to improve adverse drug event recording, transmission, and utilization to improve the overall safety of the care that is provided. So, with that introduction, our first speakers today are from the HRQ, Noel and Erin will be speaking to us about a number of projects that they have going on for documenting and measuring adverse drug events. And then, we're going to go on and hear from Zach, Med Star Health, which is also working in this space. And we will hear from him. These are going to be brief presentations.

If we have time for a couple of questions at the end of the presentation that will be fine. But to stay on schedule, what we'd like to do is hold the questions towards the end where we can all engage together after the material has been presented. We also have Joella Roland from CMS who is going to be talking to us about some new updates that CMS has proposed to the prescribing standards. And there may be an opportunity for our task force to provide public input to that process. And then, we should have time in the end for our usual discussion and public comment. So, any questions or comments about our planned agenda? Great. All right. Then, let's go ahead and proceed. Erin and Noel, you guys are going to be starting us off here.

Erin Grace - AHRQ - Guest Speaker

Okay. Thank you very much for the opportunity to talk with the task force. My name is Erin Grace and I'm the deputy center director for the Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality. And we'll try to talk very quickly through these slides. On the first slide, ARC, and CQIPS, just to give you some background about ARC, ARC is the lead federal agency for patient safety. And we do most of our patient safety work in the center where Noel and I work, which is the Center for Quality Improvement and Patient Safety. We have five divisions in our center including three patient safety divisions. One is the general patient safety division, healthcare-associated infections division, and the patient safety organization's division.

Those are our three patient safety divisions. Also, within our center, we support the national healthcare quality and disparities report as well as recently has been added to our center the quality indicators program and also the CAPS and SOPS surveys on patient experience and safety culture. You can move to the next slide. What we've been doing at ARC, I think why we were invited to this task force meeting is that we have partnered with CMS for the last number of years to estimate the annual national hospital-acquired condition rates. And I have a link in this slide here. You can look at the reports that we have been putting out. Noel has been the person who has been our main point of contact for putting out those reports.

And the way we come up with these national estimates is through a medical record abstraction process.

Medical records that come to CMS and through the clinical data abstraction center, humans are looking at those medical records and abstracting them based on questions in a system called MPSMS, which stands for the Medicare Patient Safety Monitoring System. And this system has been in place for, I think, close to 15 to 20 years. And we've been working on a new system called the Quality and Safety Review System to take the place of MPSMS with a couple of advantages. Two of the advantages being that it's a QSRS we can make available to local hospitals if they wanted to use the same algorithms that we're using to estimate the national level. The other thing is that the QSRS system calculates the rates. That's part of how the software is built. And one thing we've been doing is exploring the feasibility of automating at least some, ideally all, of the abstraction so we wouldn't need humans to do the abstraction.

We contracted with an organization called Clinovations to explore the feasibility of automating abstraction. And here is a link to that report. And we're right now doing a proof of concept for e-abstraction of a single module. I think we have 11 or 12 modules in QSRS. If you go to the next slide, this proof of concept that I mentioned is our current project with Clinovations. And the module that we selected to try to e-specify is hospital-acquired C-Diff infections. And so, we went down the road of e-specifying that module using the ECQM model. So, we've been working in the VSAC and with the QDM and the CQL and the HQMS and I can sort of read those acronyms. And I've learned a bit about how that all works together. But that is not our area or expertise. And what we have found because this is a proof of concept and we're considering how to use this model to automate more of the modules, it's been a time-consuming process.

And at least for the C-Diff, we looked at the value set authority center and there wasn't really a value set that met the needs for monitoring for hospital-acquired C-Diff. And so, we had to create some new value sets in order to do that. And so, we've only explored this one. We haven't explored the medications module, the adverse drug events module. And perhaps there are some more value sets that we could reuse related to that. But I was just trying to give you an overview of some of the work that we've been doing. And now, Noel is going to talk more specifically about our adverse drug event module and how that's working.

Noel Eldridge - AHRQ - Guest Speaker

Okay. Thank you, Erin. Can you guys hear me all right? I'm on speaker phone but I think I get a better signal this way.

Steven Lane - Sutter Health - Co-Chair

You're coming through fine, thanks.

Noel Eldridge - AHRQ - Guest Speaker

Okay, good. And I can't see the Adobe Connect so I'm just going to say next slide. So, we're on Slide 5 now, which is the MPS **[inaudible] [00:11:32]** adverse drug event excerpt. So, this slide shows in an algorithm or a flow chart the basics of how we try to measure the

hypoglycemic events in MPS and NAS. So, there's a series of questions and the software that's up on the screen in a big data extraction center. And people have physical charts or they have another screen. They have two screens. And the second screen has a PDF of the chart. And they go through the chart and they try to answer the question. So, for example, most of the patients are receiving insulin during the hospital stay. Did they get this during the stay? If it's a no then, you're out.

And the software goes on to the next question and asks about other things. If it's yes, it asks was the glucose tested. Probably 99 point something percent if you get glucose, there's a glucose test. But if not, you can't have an adverse event because we don't know the glucose value. So, we throw those out. And then, so on. If it goes under 50, if it goes under 70, there are other criteria that go on there to say whether you had the event or not. So, that gives you a sense of how that works.

Steven Lane - Sutter Health - Co-Chair

I'm sorry. Can you tell us again what does the MPSMS acronym stand for?

Noel Eldridge - AHRQ - Guest Speaker

Yeah. It's the Medicare Patient Safety Monitoring System. It was set up under the Medicare umbrella starting in 2002. And ARC took control of it in 2009 after CMS didn't want to fund anymore. And then, it became a joint program, basically, in 2010/2011 or thereabouts after CMS started the Partnership for Patients Program. And then, they were financing some and we were financing some. But it's a system, if you go to the next slide, we've written a number of papers on and you can Google it. And the first one was probably our most referenced paper. It was in the *New England Journal* in 2014 where we tracked adverse events in Medicare patients from 2005 to 2011. So, that's Slide 6. You can see a little box there. And you can see the different adverse event types that are adverse drug events.

So, for example, the hypoglycemic one I showed you before, in 2005 and 2006, you can see there were 72 events in 550 people. In 2007 and 2009 combined, there were 100 events in 866 people. And then, you can see in the different drug types, there is a different denominator because different patients are exposed to different drugs. What's the word we use whether it's a drug or a procedure, we just call them whether they were exposed to that event or not. Basically, whether they got the denominator or not. So, that's one thing we do with the data. We probably should research findings and try to look at trends. And then, the second thing we do is we produce this national rate of hospital client conditions, which is a composite of 27 adverse event sites, 21 of which come from MPSMS. Actually, 28, 21 of which come from MPSMS.

And we put out the national estimate as to how many health in client conditions there were. And you can see that table there is a little excerpt from that in 2014 or 2015 data. And that's on Page 6. On Page 7, it shows the new system we're developing, this QSRS. This is also a software tool. But as Erin mentioned, this software tool doesn't just feed up questions and take the answers and help figure out the events. It actually produces the rates afterward. So, with MPSMS, after you're done entering all of the questions, what you've got is a huge database of yeses, noes, lab values, things like that. And then, that has to be analyzed by a

special team using SAS where they take all of those numbers and they create ways to turn those answers into adverse event rates and so forth. With QSRS, that's all built into the software.

So, you answer all of the questions and it spits out reports as to how many people had adverse events. And you can see there are 11 types listed here of different categories of adverse event types of exposures to adverse events. And what we're talking about today is the medication module. That's why it has the red arrow pointing at it. So, the next one is just to tell you what's in the QSRS medication module. There are three main types that are underlined there. There are anticoagulant events. There are three types of anticoagulant events in the anticoagulant section. There's a hypoglycemic adverse event. There's an opioid adverse event. These are aligned in three priorities in the National Action Plan for reducing adverse drug events that came out a few years ago. And then, we also looked for adverse drug reactions like strong allergic reactions or overdoses that are conspicuous in the records.

And then, we have an option in the last one you can see there for unprompted free text inputs like GI bleeds from nonsteroidal anti-inflammatory drugs, delirium associated with Benzodiazepines and so forth. So, if the person going through the chart and answering the questions sees any conspicuous events that they weren't asked specific questions bout, they could put them in as free text. And, of course, that's not going to be very repeatable from one person to another. But we want to at least give them that opportunity. This is intended to be used at the national level at the Clinical Data Abstraction Center that CMS runs for producing national rates of hospital client positions but also at the local level. If people want to use it at their own hospital, they can. So, that way they can use it for case findings in addition to printing out rates.

So, they might want to know if they have a problem Benzodiazepines. They don't have a rate for that but they could look through their data and see if their abstractors are finding issues with Benzodiazepines. If they have a really bad even, they can go back and say have we had any of these in the last year. They can see what the abstractors have put in. The next thing is just a little excerpt from QSRS of what the Warfarin adverse event looks like. At the top, I put A and B just to simplify it. But, basically, a patient when he receives Warfarin and they have some conspicuous lab result related to Warfarin, in this case, it's the value called the INR that goes over five. And then, there's an indicator that the physician thought this was a problem and did something like gave them a blood transfusion because they think they're bleeding at a level that's dangerous.

And then, there's another thing. Letter B, there's another thing that we use to count that event as an event, which means it meets certain criteria. There's a notation of a GI bleed or something like that or hemoglobin drop. So, there are things in there that you're looking for. If those fit the bill then, it counts as an event. And you can see we wrote a paper on this and published it in the MPSMS version of this measure. And then, a hypoglycemic event is simpler. Basically, any blood glucose under 50 is an event. And then, any blood glucose under 70 that meets some certain criteria is also an event. Of course, after receiving insulin, not just in anybody. And then, the opioid adverse event is the last one I'm going to talk about. This is a new one that we've developed with no precursor for the MPSMS. So, what we have here is, basically, somebody is getting inpatient opioids in the hospital.

These are all inpatient measures. And they get IV Naloxone, which is also called Narcan. And then, we have three exclusions so that we don't count every use of Narcan because Narcan can be used for other reasons other than an opioid overdose that's a dangerous overdose. So, for example, sometimes they use Narcan or Naloxone after a surgical procedure to help the patient wake up because they've been on opioids during the procedure. They'll use the Narcan to help them become alert more quickly rather than over an extended period of time. That's not an indicator of an adverse event and we don't want false positives from that. And then, the other two are respiratory arrest or becoming unresponsive. So, somebody gets an opioid and then, becomes unresponsive or stops breathing, we want to count that as an event.

We don't want to only count Naloxone uses, which would be a nice, easy way to measure it because if you give somebody an opioid and you give them too much and you kill them and you don't realize what's happening and you don't even give the Narcan that Narcan use is not a good measure of the opioid adverse event because the patient is dead from an opioid adverse event and they never got Narcan. So, that would be kind of a bad measure. But we don't want to just depend on the Narcan use as a measure. And that's all we have. We have some questions. We have some backup information. But that's what we have for today.

Steven Lane - Sutter Health - Co-Chair

That's wonderful. Thank you so much. And I think that when we come back to questions, there will probably be a number. But I appreciate you laying that out and sharing it with us. Why don't we go ahead, in the interest of time, and move over now to the next speaker who is going to be Zach Hettinger from Med Star who has also been working in this area of identifying and documenting adverse medication events?

Zach Hettinger - MedStar Health - Guest Speaker

Hi. Thanks so much for the introduction. So, I wanted to thank the task force for the opportunity to speak on the detection of adverse drug events. Again, my name is Aaron Zachary Hettinger. I'm a physician researcher. I take care of patients in an urban Emergency Department in the Baltimore area. And it's rare that a day doesn't go by when I don't see the impact of adverse drug events. I frequently see patients with severe bleeding episodes from anticoagulants, critically low blood sugar, some diabetic agents, and oversedation and cardiac arrest from opioids. In addition to directly caring for patients, I'm an assistant professor of Emergency Medicine at Georgetown University and serve as the medical director and director of cognitive informatics for Med Star Health's National Center for Human Factors in Healthcare.

Our human factors center consists of approximately 30 individuals with expertise in diverse disciplines such as cognitive psychology, industrial engineering, computer science, human-computer interaction, and clinical medicine. As the largest human factor center embedded within a healthcare system, we integrate our scientists with clinical experts to better understand and study the impact from systems based perspective. My research has been funded by a number of federal, state, and nonprofit entities in full disclosure. ARC is one of those as well as Office of the National Coordinator, Department of Defense, two charitable

trusts, and the American Medical Association. As we consider the challenges with detecting adverse drug events or any other serious event, I often like to use the iceberg analogy to break down the problem as we start studying specific events problems and patterns.

The tip of the iceberg represents the most catastrophic events. For example, as we were just hearing in the previous presentation, patients with critically low and sustained blood sugars can end up having significant problems, including seizures and potentially death. And these catastrophic events are often detected and frequently captured in the healthcare systems patient safety event reporting tools. These patient safety event reporting tools, the healthcare systems use to capture self-reported safety events from front line clinical staff. These systems are purposely separated from the electronic health record to keep quality assurance programs and internal event reviews free from legal discovery in the event of legal claims, which sometimes makes these data sets difficult to obtain for research purposes.

These reports themselves often contain a paragraph or two usually from the perspective of the team member involved in that particular report and can provide very valuable information and firsthand knowledge around the circumstances that led up to that adverse drug event or any safety event. These reports are critical to healthcare organizations to identify and act on safety events but, again, can be challenging to analyze on a large scale often due to the unstructured data that's present. Our research team has pioneered some work in this arena using machine learning techniques, specifically, **[inaudible] [00:23:51]** the processing to systematically analyze patient safety reports for both adverse drug events as well as challenges associated with electronic health records.

This is an emerging field that could augment adverse drug event reporting systems in the future and potentially lead to early detection for new adverse drug events as well as hypothesis generation. Just below the surface of this iceberg that I mentioned lies those events that aren't necessarily in the patient safety event reporting system but are likely represented as signals within the electronic health record. Again, kind of leading on some of the discussion that we just had. And these events may either not be recognized as adverse drug events or they may cause no lasting or significant harm to the patient or potentially a near miss that a nurse or doctor caught before they led to an actual adverse drug event but certainly could have resulted in significant patient harm. As I mentioned, these types of events likely leave signals in the electronic record that can be analyzed by detection algorithms.

For example, to build off the prior event, low blood sugars or hypoglycemic events can be detected in the QSRS project. But these models can get complicated very quickly as we attempt to increase the sensitivity and specificity of the detection tools. These temporals and analysis require close collaboration between clinicians and informatics professionals to ensure that the analyses are clinically valid and often require individual chart review. Further considerations include patient comorbidities that may have contributed to adverse drug events or compounded the event. It might not be clear if it was related to the specific drug or other external factors. The other challenge is that most electronic health records are not designed around this degree of data analysis and surveillance.

Most EHRs were designed around storing individual patient transactions. For example, storing a set of vital signs or lab values for a patient but not rapidly reviewing millions of records across different geographic locations and points in time and then, comparing those relationships in those data elements. There are definitely solutions that are in the process from government agencies like ARC, individual healthcare organizations, EHR vendors and third-party software companies. But there aren't any universal solutions at this time. Now, the role of the healthcare information exchange systems can also play a critical role in connecting EHR data elements across healthcare organizations, HIE systems, and other clinical data connections like electronic prescription systems, which I believe we'll be hearing about later, and prescription drug monitoring programs, PDMPs, for controlled substances can play a critical role in identifying and preventing adverse drug events.

This is critically important in the area of opioid safety. The standing up and importantly the integration of PDMP systems into the EHR can play a key role in detecting both high-risk patients and adverse drug events that have occurred. Our review systems are often focused on direct clinical care patients and have less often been utilized for reporting and surveillance systems. And more work and support is needed in this area to detect those events that may take place across care settings and healthcare organizations, often a blind spot in current EHR based studies and surveillance systems. I also wanted to talk about the base of the iceberg that I believe is represented by the many events that are occurring in outpatient and ambulatory settings but may not be represented well in the electronic health record but that patients often recognize as a potential area for discovery.

At a national level, there has been interest in patient-reported outcomes but we are still early in building these systems that can capturepatient-reported outcomes and also integrate those into the electronic health record. For example, the integration of a patient obtained glucose measurements or 9-1-1 visits by an ambulance that don't result in transport to the Emergency Department could be detection events for minor hypoglycemic events due to insulin or other diabetic agents. This proactive approach has the potential to prevent more severe episodes that will require visits to the Emergency Department or potential hospitalizations and permanent harm. In addition to the iceberg analogy that I laid out previously, I'd like to also layout for the task force a more holistic approach to the detection and prevention of adverse drug events.

In primary care, the prevention of cardiovascular disease is an important aspect of clinical care that we like to apply to the safety event realm. It starts with primary prevention, namely the promotion of a healthy lifestyle with exercise and smoking prevention. And then, secondary prevention focuses on the management of risk factors like hypertension and diabetes. Finally, tertiary prevention in cardiovascular care occurs after the patient has had that cardiovascular event like a heart attack and the medical team seeks to reduce the long term impacted damage to the heart through cardiac stenting and other interventions. However, in healthcare, we often tend to focus on tertiary prevention as it relates to safety focusing on those most severe events.

However, using the lens of primary and secondary prevention, we can seek to impact adverse drug events by monitoring not just the adverse events themselves but also seeking to understand the circumstances that create the hazard, namely primary prevention. And once

that hazard is in place, how do we prevent it from harming the patient, secondary prevention. So, not only can we use the detection algorithms as described above to detect hazards and safety events that have happened but we can also seek to understand the context in which those events happen, including the usability and safety of electronic health records and their potential role in facilitating and/or preventing safety events like adverse drug events. Through research sponsored from ARC, our team has piloted a pairing of detection algorithms with EHR screen recording technology to review the user interface of EHRs to understand how these complex systems can contribute to and prevent those errors.

This area of research is in its early stages but I believe it can lead to significant long-lasting improvements to reduce adverse drug events and assistance based approach. Some of our recent published research in the Journal of American Medical Informatics Association in July of last year showed the EHR usability can have a major impact on safe and efficient ordering of medications including the discovery of errors in assimilated setting of up to 50 percent when placing orders for medications. Our team also saw significant variability across EHR vendors and clinical sites for the same medication orders showing that the implementation of the electronic health record has a major impact on potential safety events like adverse events.

The development of resources like clinical use cases, testing scenarios, and post-implementation surveillance of EHR usability will be important for optimizing the contribution of electronic health records in this area. In closing, thank you for this opportunity to discuss some of the research and potential areas for exploration in the detection of adverse drug events. And I'm happy to take questions if time allows.

Steven Lane - Sutter Health - Co-Chair

Zach, thank you so much. That was rapid and remarkably thorough. You didn't submit any slides but, obviously, you were speaking from some notes. It would be great if you could share your materials with the task force so that we'll have reference to them. We'll, obviously, be putting together some minutes and trying to encapsulate what you said but I'm sure even with our recording, it's going to be hard to get all of that. So, we would welcome any materials you could offer to support that.

Zach Hettinger - MedStar Health - Guest Speaker

Absolutely.

Steven Lane - Sutter Health - Co-Chair

So, we remain on our schedule. And I'm very much hoping that our presenters will be able to stay with us to participate in some Q&A. I certainly have been jotting down a number of questions and I'm sure the other task force members have been as well. But we did invite some folks from CMS. There has recently been a new publication by CMS looking at upcoming changes related to the e-prescribing standards. And we wanted to give Joella Roland a chance to walk us through those so that we can consider whether this is an area that the task force wants to spend any time focusing on. So, Joella, do you want to make your presentation?

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

Sure. I'd be happy to. Can everyone hear me?

Steven Lane - Sutter Health - Co-Chair

Sounds good. Yes.

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

So, my name is Joella Roland and I'm the lead for this rule. The rule specifically that I'll be discussing is secure electronic prior authorization for Medicare Part D. The number is CMS 48189P. And this was published in the Federal Register last Wednesday on June 19, 2019. Now, because this is a proposed rule and it is out for comment, just like any other proposed rule, I'm explicitly prohibited from engaging in any detailed discussion about this. So, I'll just be briefly presenting the information and reiterate the opportunity for public comment. And all of the information that I'll be discussing is available in the proposed rule itself. So, this rule is based on the Support Act, which stands for the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patient and Communities Act.

And this was passed on October 24 of this past year. Section 6062 of the act requires that CMS name a new transaction standard for the Part D e-prescribing program by January 1, 2021. This rule follows that Support Act mandate by naming the standards. Specifically, it names the National Council for Prescription Drug Programs, NCPDP Script Standard Version 21707.1. If this rule were to be finalized, it would amend the Part D e-prescribing regulations, specifically 423160B to require that Part D plan sponsors to support this version for use in EPA transactions with prescribers regarding Part D covered drugs to Part D eligible individuals. If this rule were to be finalized, prescribers would be required to use this version of the NCPDP Script Standard when performing EPA transactions.

This proposed standard would provide for the electronic transmission of information between the prescribing healthcare professional and Part D plans to inform the sponsor's determination as to whether or not a prior authorization should be granted. It would allow prescribers using an electronic prescribing system, an electronic health record, or a portal to determine whether the beneficiary's plan requires prior authorization for a given medication. If the prescriber enters the prescriptions into the ERX system, a message would be returned to the provider indicating that prior authorization is required. Use of this EPA transaction would then enable the prescriber to submit the information required to fill the terms of the prior authorization in real time, which is in contrast to the current other prior authorization method. This standard would begin on January 1, 2021.

As of January 1, 2020, plans would already be required to use the NCPDP Script Standard 201707.1, which is the same standard that we're proposing in this rule for certain Part D specified transactions. So, we believe that giving plans an additional year to add electronic prior authorization to that list would not be overly burdensome and it would help ensure the Support Act mandate. The benefits of this would be that it would increase the use of EPA. And when EPA is implemented, the current system of manual processing via fax and phone calls would be eliminated since plans would be able to use this more appropriate standard for transactions. This standard is more appropriate for Part D rather than the currently

approved HIPAA standard, which is the X12278 standard.

Now, I know this was a very brief overview because as previously mentioned, I'm barred from giving any more detailed information than what's available to the public. But if you have any comments about this rule, they must be shared publicly through our comment process and be received by 5:00 on August 16. They can be submitted electronically via regulations.gov or via regular mail. Thank you all very much.

Steven Lane - Sutter Health - Co-Chair

Thank you, Joella. And that was very fast and furious. Can you just go back and clarify again what are the compliance dates that you have in the proposed rule?

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

Sure. So, the compliance date in the proposed rule and this is, again, a proposed rule so if it was to be – and this is all assuming it's finalized as proposed. The proposed standard would begin on January 1, 2021. The standard that I had mentioned January 1, 2020, was in a previous rule 4182F, which was published in April 2018. And that had made that requirement for other transactions. So, our thought process was having this proposed standard begin on January 1, 2021, would not be overly burdensome because the standard for other transactions is set to begin on January 1, 2020.

Steven Lane - Sutter Health - Co-Chair

And that January 2020, that's in a final rule, not a proposed rule, right?

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

Well, it's in both. It was proposed and then, the final rule finalized it as proposed.

Steven Lane - Sutter Health - Co-Chair

Right. So, that one is happening. It's in the books. Those requirements for 2020. And then, this would be the following year in 2021 for the EPA standard.

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

Exactly.

Steven Lane - Sutter Health - Co-Chair

Okay. All right.

David McCallie - Individual - Public Member

Steven, I have a clarifying question for Joella that I think she probably is allowed to answer. And this is my lack of knowledge of that particular NCPDP Script Standard. But you specified that the provider could submit information in real time. And I just wondered if you could describe how they would that. Is that done using the standard or would they do that through some out of band mechanism? How do they submit real-time data?

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

I can't get into the details of it. What I can say is that the logic behind the standard would enable real-time submission. But I cannot get into the details of exactly how this standard would be implemented, how it is implemented via EHR versus portals. I can't get into the details of that.

Arien Malec - Change Healthcare - Member

David, this is Arien. Conceptually, it's very similar to an eligibility check that's already used in e-prescribing. And it's also conceptually very similar to the NCPDP B1 transaction that's already routinely used by pharmacies and PBMs, PDPs, to actually adjudicate benefits in real time. So, the intent of this standard, the NCPDP Script Standard, is to put another pipe into those existing workflows that surface the EPA requirements that are already surfaced through the B1 transactions.

David McCallie - Individual - Public Member

You can do that by putting questions in front of the clinician. The prior authorization could involve potentially complicated conversations with the provider. How does it do that? Is it an app?

Arien Malec - Change Healthcare - Member

As was described, it surfaces the requirement for EPA. And then, the actual mechanics of collecting and submitting the information would be out of band.

David McCallie - Individual - Public Member

Okay.

Clement McDonald - National Library of Medicine - Member

This is Clem. Is there any way to get a look at that standard, the NCPDP standard? I'm not looking for secrets but some of the other standards are easier to see or find.

Joella Roland - Center for Medicare & Medicaid Services (CMS) - Guest Speaker

It's my understanding that that standard has been published but, again, I cannot get into how you would access that standard.

Clement McDonald - National Library of Medicine - Member

No. I'm not acting for secrets on that. It's 2017, which is now two years ago so I'm betting it's been published. The question is, not to you but anybody on the committee, how can one get access to read it? Is it on the web?

Arien Malec - Change Healthcare - Member

Yeah. It's an NCPDP Script Standard and you have to be an NCPDP member in order to access the standard. There may be organizations that have implementation guides around that standard. And, again, you'd have to be working with those organizations. And I believe that NCPDP requires a membership fee in order to access standards. But your organization may

already have that membership fee. And then, ONC has historically been able to get access to standards for review on a limited basis. And that might be an avenue that we could potentially explore.

Clement McDonald - National Library of Medicine - Member

Okay. Actually, that came as sort of a surprise. I heard that a couple of weeks ago. I thought that the federal standards all had to be freely available. And there's no way to review them or comment on them if they aren't.

David McCallie - Individual - Public Member

That would be nice, wouldn't it?

Steven Lane - Sutter Health - Co-Chair

So, that's a very interesting observation that some of these standards, the NCPDP standards are not generally available for public review and understanding. I hadn't realized that either. That may be a good recommendation for our task force. So, thank you, again, Joella, for the presentation. I really appreciate that. And as you saw, we did bring up the posted NPRM and I think also did post that in the public chat. We've been getting some public comments here from somebody, Patrice, who clearly knows what's going on here. And perhaps when we get to the public comment time, Patrice, you can share some of your insight with us then. That would be great. So, that brought us to the end of the planned presentations. And we now do have time for additional Q&A.

Feel free, task force members, to use the hand raising feature, and we will give people a chance to chime in. I think that given that there are no hands up presently, I will start in and come back to Erin and Noel. Clearly, you guys are managing the progressive advancement of a very challenging process to go through and manually review medical records to identify these adverse events. And you figured out ways to find them and categorize them and count them. But clearly, the number that you're able to review using this manual process is substantially smaller than the number of cases that are out there. And you're looking at hundreds of cases as opposed to hundreds of thousands of cases. And it sounds like you're going through a process to streamline this, to automate it in some way.

But I think as you called out, this is an old fashioned if you will, 20th century process of doing chart review and doesn't really seem to rely heavily on the fact that we've all implemented electronic health records and there is now digital data being captured. Certainly, most medications, lab results, vital signs, a lot of information is available in a purely digital form in addition to a lot of the free text notes that are there. And we heard some people reference natural language processing. But as you've been exploring this area, have you been identifying or looking for opportunities to really fully automate the process, which would potentially allow for the analysis of orders of magnitude, more data to find additional signal in the data than what is possible using this manual chart review methodology?

Have you started to compile any kind of a wish list or observations where potentially data standards or transaction standards could come into play to substantially change our ability to identify and manage these adverse events?

Erin Grace - AHRQ - Guest Speaker

This is Erin. I can take a stab at that and then, Noel can jump in. I don't think we really have necessarily a wish list. But I think the report on automation feasibility study that we did in 2016, they went into QSRS and they looked at all of the questions and examined about a half dozen different medical records to see where the answers to these questions could be found in the medical record. And what they learned was a couple of things. One thing that they've learned was, often, these are in multiple places. And the second thing was it's not necessarily a standard across various EHR products. I don't know if you have it up on the screen but we have a couple of background slides that we didn't speak to. And the first one – well, there's a slide where the title is Key Points from Automation Feasibility Study Regarding the Medication Module.

And this is just to give an example of some of the challenges to fully automating this process. And so, Clinovations analyzed all of the QSRS questions and grouped them into five categories regarding how the information is stored in the electronic health record. So, either it was a numeric value, it was structured data and coded, structured and uncoded, structured free text, and unstructured free text. And those last two, even the structured free text but definitely the unstructured free text, requires natural language processing to get at that information. And as an example in the medications module, at the time that they reviewed it, we've been modifying the system since then, there were 64 questions.

Of the 64 questions, only 3 had a numeric value, 14 were found and the answers were found in structured uncoded data, 15 were in structured and uncoded data, and then, 32 were free text either structured or unstructured. So, that can sort of give you a sense of – yeah, the slide before, Slide 14. Yeah, this one. So, I guess that would be a place to start in terms of a wish list for either transaction standards or standards to help tease this out at least for medications.

Noel Eldridge - AHRQ - Guest Speaker

The only thing I would add to that, I think it was a very good answer, Erin, thank you for giving that to the group, from my standpoint, our sample – if I simplify the rate, we get basically 1 in 1,000 charts. We've been getting around 30,000 charts from people 18 years old and over for a year and there are around 30 million discharges in that group. But we get around 1 in 1,000 charts from 400 to 800 hospitals per year. And we've had various samples over the years to look at different groups and so forth. But there is some number of companies out there that are trying to do different services for making different products and selling them to clients. But they're not very eager to tell you how they do it. We've tried to approach them to try to understand what they're doing.

One I think is that it's proprietary. They don't want to give away their secret. And I think the other thing is that they don't want us telling them that their data is no good because they don't – they might do something like cancel the Narcan uses. Well, canceling all of the Narcan uses is not a good measure because you don't want people to not use Narcan when they need to use it because it's going to be counted as a demerit against the provider or the facility or the team or whatever. And then, there are plenty of good times to use it that are

not opioid overdoses it seems. But there are a lot of tricky things out there. And I think to be respectful of these companies, as I said before, they have proprietary things they've developed. There are a billion people working there. They've figured out all kinds of neat things. They don't want to give that away.

And then, also they don't want to be told by ARC that their measures are no good. And then, if they're going to be honest if they say have you reviewed this with ARC, they're going to have to tell people that ARC is very critical of the thing or something. So, that's how I see it.

Steven Lane - Sutter Health - Co-Chair

Thank you. We've got a number of task force members with questions in the cue. So, we're going to go to David McCallie.

David McCallie - Individual - Public Member

Yeah, thanks. And to the presenters, all of you, thank you for really excellent presentations. I really learned a ton. But I have just a broad question on where is the lowest hanging fruit or maybe in the iceberg metaphor, what part of the iceberg should we focus on. And maybe, Zach, I'll direct it to you but, obviously, anyone feel free to weigh in. And that is you can imagine that adverse drug events could fall into some broad categories the remedy for which would be quite different. One category could be it's just an unexpected response by the patient. It's unpredictable. Perhaps a genetic variant that was unknown. Another category could be it was an actual error in clinical judgment. A clinician just made a mistake, didn't think the patient through carefully.

And then, a third category could be that everything was correct, except the user interface, the user experience, led to an error by poor design. And I'm sure there are other ways to divide it up. But, Zach, is there some rough breakdown of what's the highest proportion? Are they mostly due to user experience problems? Are they mostly due to unpredictable things? Are they mostly due to clinical judgment failure? Or is that a fair way to even ask?

Zach Hettinger - MedStar Health - Guest Speaker

This is Zach. Oh, sorry. Is someone else talking?

Noel Eldridge - AHRQ - Guest Speaker

I was just going to say let me **[inaudible] [00:53:50]**. I didn't now who that question was for. There are a lot of taxonomies. What you just proposed would be one taxonomy. I think, in our eyes, there must have been – a lot of the time, the drug is given with the intended dose for the intended patient, with the intended round, at the intended time and all of these things. And then, still they have an idiosyncratic response or they have a response in retrospect what would have been knowable **[audio interference]**.

David McCallie - Individual - Public Member

We're losing you a little bit.

Noel Eldridge - AHRQ - Guest Speaker

Okay. Let me let the other guy talk and then I'll – I've got a bad connection here in West Virginia.

Zach Hettinger - MedStar Health - Guest Speaker

Hi, this is Zach. I would agree that there are some taxonomies out there but I don't think we really know necessarily the distribution. And often times, what we're really focusing on right now is just the detection piece in and of itself. And it's challenging to try and figure out what was preceding it. So, that's definitely where some of our research is headed right now. But I think that is somewhat complicated but important using your metaphor, the low hanging fruit, to go after so that we can make those changes because what we don't want to do is just kind of come up with some detection and then, not be able to give any guidance on that distribution or where we think the best efforts are focused on. And so, there is going to be some degree of distribution across those examples that you gave.

But it does get complicated. And to kind of build off one of the prior points with the Narcan usage, some of our work had been looking at that. And when you get let's say a patient who comes into the Emergency Department in an acute opioid overdose from either illicit drugs or prescription drugs and they get brought in, we will immediately give Narcan to treat that patient. But in some instances, you might need to give them opioids afterward if you reverse too much of the opioids in their system. And so, we'll see instances where patients, essentially, are documented as given an opioid and Narcan at the same time in the structured data. And it might be difficult to tease out chicken or the egg, which one came first because the patient was so critical that the providers were focused on taking care of the patient and not on documenting things in the electronic health record in a critical situation.

So, there definitely is a role for trying to understand those from either chart reviews or machine learning, natural language processing to understand the sequence of events that sometimes aren't necessarily captured in the structured data. So, to get back to the original piece on where I think we should focus, it's building these detection algorithms that, not only detect but also start to give us some hint as to where the issues are most likely arising from. And sometimes that doesn't necessarily have to be a big data approach. It can be doing some of these kinds of smaller observational studies or looking in the patient safety event systems before finding that there are a lot of mentions of electronic health records in the care of patients that are having hypoglycemic events.

Maybe we need to look into that a little bit further if the information is being displayed inappropriately or there are dosing issues or what have you. I think we can start to kind of tease out those low hanging fruit pieces. But I don't think it's entirely known yet.

Steven Lane - Sutter Health - Co-Chair

Thank you, Zach. And we've got a couple of other questions in the cue. I just want to ask a quick follow up on that, Zach. One of the things that our task force has discussed has been the pros and cons of discrete SIG data, especially in the ambulatory setting. I think most inpatient EHRs, you've got all of the discrete data captured, dose, route, frequency, etc. But in ambulatory EHRs and in a lot of the transactions that go back and forth around e-prescribing, some of that discrete SIG data is lost or never entered in the first place. And we

rely on free text things. Has your group identified a need for discrete data, especially in ambulatory prescribing as something that would have a substantial impact on our ability to identify adverse drug events?

Zach Hettinger - MedStar Health - Guest Speaker

I can't say that we exactly studied that specific area but we definitely have noted it in the past as we've been doing some analyses and that has prevented some degree of analysis as well as, and as I mentioned during my comments, about connections between systems and trying to look across healthcare organizations or across the EHRs if it's stored not in discrete elements. It makes it very challenging to understand and compare across sites. So, I definitely think that containing those discrete elements would be helpful in teasing that particular issue apart.

Steven Lane - Sutter Health - Co-Chair

Thanks. Noel.

Noel Eldridge - AHRQ - Guest Speaker

Yeah. One thing I was hoping to follow up on is for several years, we've been using these measures. And we communicated these measures out to a lot of hospitals as they were being used in the national rate of hospital client conditions. And I don't know for a face but I think over this time, some people have started to look at some things on some data points in ways they didn't previously look at them. So, for example, the blood glucose, I think people started to monitor cases under 70, cases under 50, track those, put numbers on them, put rates on them, feed them back to the system and then, maybe monitor people again under 80 and then, say okay, this person is under 80. Let's not let them go under 70 so it doesn't go under 50. And things like this have changed.

Likewise for the INR value paper that I referenced in there. We showed that in the data we had when there was daily INR testing, the adverse events were lower because the physicians could respond faster to the numbers of the INR going up. And so, it seems like more monitoring, more paying attention to the lab values can have a positive result in terms of reducing adverse drug events, which we have seen going down over the last eight years or so.

Steven Lane - Sutter Health - Co-Chair

Thank you. Ed Juhn, you had your hand up for a while.

Edward Juhn - Blue Shield of California - Member

Yes, thanks so much. I guess the question is from the automation feasibility study, did you guys also examine partial automation as you are working towards fully automating extraction of patient information? And if so, were there any key learnings that you might be able to share?

Erin Grace - AHRQ - Guest Speaker

Yes. This is Erin. We did look at partial automation. And we haven't tested that but the tests

that we did, we know that we have to do some more development of QSRS in order – so the test we did was can we extract the information from the electronic health record. And we showed that we could do that. The second part of that that we haven't tested yet because we need to build that capability into QSRS is can QSRS accept that data that's pulled from the EHR. And so, even the test that we did with fully e-specifying a module, it would require a human then to go into the QSRS system and answer the questions. And so, I think how we've envisioned – we've sort of envisioned this as a stepwise process.

If we could partially automate maybe the low hanging fruit then, we could reduce the amount of human time that has to be looked at for the abstraction. So, I think that is definitely something that we've been thinking about. Instead of boiling the ocean, can we get there partially and then, continue to work on that as an LP evolves and other ways of pulling the information?

Noel Eldridge - AHRQ - Guest Speaker

Let me jump in on that one, too. For example, on the adverse drug events, the easiest partial automation might be just did the person get this qualifying drug. Did they get Warfarin? Did they get insulin? That would be nice if the computer could just do that. And then, maybe some of the trickier questions the person could answer. But the lab values could conceptually be partially automated, too. Then, there are things like the C-Diff, which is – I don't know if the whole group are physicians or doctors or nurses or others. So, C-Diff is a terrible infection of the colon that causes bloody diarrhea and can be life-threatening if it goes on long enough. And so, we can get a positive C-Diff test from the record conceptually. But we don't want false positives because there can be times when they do that test for no good reason.

And so, we only want the C-Diff cases that are preceded by the person is already having diarrhea. We don't want it if they're just doing a full workup on this person. And oh, by the way, they're positive for C-Diff because some people are positive for C-Diff and the have no active infection and it's not a problem. So, that would be hard to automate probably because there's probably not a field in there for loose stool or diarrhea. Maybe there is. Maybe there's natural language processing. You'd have millions of – well, not a million but you'd have several synonyms for diarrhea or whatever and that kind of thing to get it out. But it turns out to be quite tricky.

Steven Lane - Sutter Health - Co-Chair

Arien Malec, you have your hand up.

Arien Malec - Change Healthcare - Member

Yeah. Thank you. Sort of along the same lines and maybe will continue to be a consistent answer but if you could wave a magic wand and get more information up the stack from fully unstructured to partially structured to structured but not coded to coded, do you have a perspective about the additional structure that would drive more accuracy in adverse event detection?

Erin Grace - AHRQ - Guest Speaker

This is Erin, again. So, you're backing up. That's a great question and you're backing up

against at least my lack of expertise in the standards world. So, that's kind of a hard question for me to answer.

Arien Malec - Change Healthcare - Member

Yeah. I'm not actually asking for the underlying standard. I'm asking for the signals that if only you had would be more predictive of adverse events in the field.

Erin Grace - AHRQ - Guest Speaker

I think one area that we discovered with our prototype of the C-Diff module, and I don't know how to describe this exactly, but is the temporal relationships between things that happen during the care like the person who spoke from Med Star, Zach, was saying about the opioid events that sometimes you give Naloxone and then, you take out too much of the opioids and then, you might issue an opioid and it's really hard to parse that out. Even with the C-Diff, we found some of the temporal relationships are hard to pull out of the EHR.

So, we want to be sure when a person is diagnosed with C-Diff that A) they didn't have it when they came in, that it was truly hospital acquired. And B) the other key point is what Noel just mentioned that the reason they did a C-Diff test is that the patient was having loose stool or diarrhea or whatever it's called. And so, to determine was that determination made, the loose stool, before and sort of what caused the test. I think that's an area where we've struggled the most in terms of trying to automate some of this.

Arien Malec - Change Healthcare - Member

Got it. So, some of the temporal relationships between events that are really key. And as you noted, clinicians in the field think about documentation relative to the encounter but not necessarily to the sequencing of temporal events, particularly in an emergent situation.

Erin Grace - AHRQ - Guest Speaker

Yeah.

Arien Malec - Change Healthcare - Member

And I think we all know in the hospital, the relationship between an order and administration can sometimes be a little slippery.

Erin Grace - AHRQ - Guest Speaker

Right, right. That was another thing we found, too, is that an order may have been placed to put in a urinary catheter, for example. But then, something might happen where it doesn't actually happen because there's not necessarily something to document in the EHR that says if the order was placed and I put the catheter on Mr. Jones within 30 minutes of the order being placed or something.

Arien Malec - Change Healthcare - Member

Yeah. Thank you.

Steven Lane - Sutter Health - Co-Chair

David McCallie, you have your hand back up.

David McCallie - Individual - Public Member

Yeah. For Zach, you mentioned the base of your iceberg was ambulatory but you didn't say anything about FDA monitoring programs, FDA adverse event monitoring programs. And I'm curious if you think those programs, and I'm not real up to speed on them so I'll ask a naïve question, are they adequate? This is drug surveillance in general. Could you make comments about how they could be factored into this overall space?

Zach Hettinger - MedStar Health - Guest Speaker

This is Zach. So, I certainly couldn't give you a broad overview of all of FDA's programs. We are currently working on a research subcontract from the FDA where they are exploring the use of not just claims data where their Sentinel program has primarily been using claims data but now, they're starting to explore the use of EHR data using some of these similar techniques that we talked about earlier. I don't know how much I'm at liberty to kind of go into details but they are very interested in understanding these temporals and analyses and machine learning and so forth. So, it's definitely being explored. I couldn't speak to the adequacy or anything along those lines but there is a lot of interest. But as I kind of laid out, there are a lot of challenges with looking across institutions in standardizing the data and abstracting the data out of these systems.

I think there is a lot of new technology that's being implemented and a lot of potential down the road. But most healthcare systems or many healthcare systems are not quite there yet. So, this is definitely an evolving space. But I think anything that this task force can do to help facilitate the detection and consideration around data, the e-prescription, I think, is a great example, being able to monitor this is critical because right now, it's very challenging and we certainly are running up against that in multiple research projects on our end of how do you standardize across institutions and the type of data that's coming out. I didn't talk too much – there are things around standardization using the Fyre SHIR standard for interoperability of applications within the electronic health record. So, that is an emerging standard that can help with cross-connection of data sets.

So, that's one potential area. And the other part of your question around the basic pyramid or iceberg or what have you, I'm particularly interested in this area of patient-reported outcomes. And I think there are tons and tons of data that's going on out there that the patients know that they're having these kinds of subclinical events or they know they're having low blood sugar problems. And I'll often take care of these patients in the Emergency Department and say yeah, I've been having low blood sugars for the last couple of days or yeah, I had an event yesterday. And I was unconscious and my family member called the ambulance and they came and gave me some glucose and I felt better so I told them I was fine. And then, 24 hours later, they have another event.

So, I think that there is a lot of other data that we need to kind of be thinking about down the road and integrating. And there are some pilot projects out there trying to use cellular-based glucometers or internet enabled glucometers as the technology evolves that maybe could

start to report those outcomes automatically so we can catch things much earlier rather than waiting for these kinds of catastrophic events where patients get brought into the Emergency Department.

Steven Lane - Sutter Health - Co-Chair

Zach, you definitely touched on some things that we've been spending a lot of time thinking about, especially around Fyre, which is clearly an evolving standard to support a lot of this interoperability. You mentioned that you're working on a subcontract with the FDA. One of the things that our task force has tried to do is to find the right people within the FDA that are working on these issues. And we've, actually, been struggling to do that. So, I don't know if you could introduce us to the lead on that project who almost certainly knows who all there is working on these issues because we may want to invite them to join us as well.

Zach Hettinger - MedStar Health - Guest Speaker

Sure. The prime awardee on the contract is IBM. So, I will talk to – I can make a connection between you and IBM and then, they can kind of go from there. They're our primary go-between with the FDA. So, I'm happy to set up that conversation.

Steven Lane - Sutter Health - Co-Chair

Thank you so much. You also were talking about patient-reported outcomes. One of our task force members is Ricky Bloomfield from the Apple Health team. Clearly, that's one of the potential technologies that we have available to us to capture patient data both reported and otherwise captured, as you mentioned, through glucometers, etc. Ricky, do you have any thoughts about this area where patient data, patient-reported outcomes might potentially fit into this capturing of information around adverse drug events? Maybe Ricky got pulled away. But I think that is really quite an interesting area. I see Ricky is no longer on the meeting. We lost him. Good. I don't see any other hands up from the task force members. Let me just look back through my notes here.

David McCallie - Individual - Public Member

Steven, it's David. If there's a need for another question, I'll ask a very broad one that just got partially touched on, which is sort of the legal and liability barriers that may be in this space. I know it's a really complicated space about reporting an adverse event in a manner that doesn't expose the hospital to liability or at least decouples the monitoring from liability. Could Zach, you say something about whether there are big problems in that area or is it well understood and it works okay?

Zach Hettinger - MedStar Health - Guest Speaker

Sure. Definitely an evolving area. I know that there has been a lot of move towards increased transparency around adverse events and safety events across the healthcare industry and kind of early reporting and early addressing and discussing with family members or patients when events do occur. I still think that's an evolution and we're not all there yet. In the past, certainly, there have been a veil or lack of transparency around some of these issues. So, again, anything that the task force could do to try to address those. In the aviation industry, there's an attempt to have full disclosure of any safety events that are notified or made aware by let's say mechanics or pilots and then, held blameless as long as they're reported

early. And, obviously, weren't willful or anything along those lines.

And that's the rare exception that would ever happen. So, if that can be supported in some way that these can be kind of protected events or there are patient safety organizations and those types of efforts that ARC and others have kind of led, whether those can also be areas for reporting and protections, I think, would address concerns that healthcare organizations might have. But yeah, I don't think we're 100 percent there yet.

Steven Lane - Sutter Health - Co-Chair

I think it's a really good question, David. And thanks for that response, Zach. I know after our last call, I explored this within our own institution. And I think ours, like most, do have this whole separate area where patient safety concerns can be registered. But then, it really is kept under wraps, attorney-client privileged, etc. I'm curious whether there are any opportunities to create a safe harbor for this sort of reporting. Is there anything that could be done with regard to federal policy to allow clinicians and health systems to better expose and be more transparent about this? Even simply focusing on reporting of de-identified data. I think the concern, of course, is that folks are going to get sued for malpractice if this information is made available.

But is there any public discussion about more requirement for de-identified reporting just to help it to expose what's going on?

Erin Grace - AHRQ - Guest Speaker

This is Erin after I just said I need to drop off. But I heard you start to talk about this and PSOs. And as part of the Patient Safety and Quality Improvement Act of 2005, as Zach mentioned, there are some protections for reporting for providers who report to a PSO. That information is protected. And the idea was that, of course, it's all voluntary and that PSOs, it's voluntary for them to submit data to ARC – well, not directly to ARC, to the PSO Privacy Protection Center with the idea that those data could be aggregated for national learning. And we could do reporting on patient safety events across the country if we have enough data to be able to do some regional comparisons or even state comparisons.

It's been a long time coming but we finally have about just under 2 million records, and a record is a safety event, that has been reported to the Privacy Protection Center and, actually, just on Friday, ARC turned on the network of patient safety databases, which after the data or unidentified from what comes in at the PSO, the data are unidentified and aggregated. So, what we have now is the first cut of data that have been submitted by PSOs. And it's not enough data to get to regional and state levels and things like that. But it's a start. And we hope that with finally being able to turn on the MPSD that we'll continue to get more data and be able to aggregate it into more meaningful information that can be used for national learning.

Steven Lane - Sutter Health - Co-Chair

That's great. Thank you for sharing that. So, we are a couple of minutes over for our public comment period. So, I think we're going to go ahead and open up the lines. Thank you, Erin. We know you have to drop off and I particularly hope that Patrice Kuppe has a chance to get

a public comment in based on her notes made in the chat window. So, do you want to open up the lines?

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer

Operator, can you open the lines?

Operator

If you'd like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue and you may press star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer

Is there anybody in the cue?

Operator

Not at this time.

Cassandra Hadley – Office of the National Coordinator for Health Information Technology – Designated Federal Officer

Okay. Steven?

Steven Lane - Sutter Health - Co-Chair

Very good. Thank you so much.

David McCallie - Individual - Public Member

It's David. I stepped away from the computer so I can't raise my hand. But I have one last comment if we have a minute. Could I ask a question?

Steven Lane - Sutter Health - Co-Chair

Yeah, go ahead, David.

David McCallie - Individual - Public Member

So, this is, again, for Zach. And it concerns the EHR and kind of a usability question. But clearly, with the quantification of some of these algorithms for detecting a possible adverse event, much of that is computable and could be embedded into decision support systems that are monitoring clinician activity, even doing something like warning you're doing something that might be associated with an adverse event. You could imagine alerts like that that would be fairly easy to create given how much of the algorithm is based on structured data. The downside of doing something like that, obviously, is physician or provide dissatisfaction with too many alerts.

And I'm curious if you think there's a way to reach balance in the space with EHRs. Should the EHRs be doing a better job of this with more of this kind of potential alerts around the possible emerging ADE opportunity? Or is that just asking for trouble?

Zach Hettinger - MedStar Health - Guest Speaker

Great question. And I think that, certainly, alerts have their time and place. But I believe there are other ways that we can enable improved functionality and safety and efficiency in the EHR. And then, one of the examples earlier around Coumadin, Warfarin dosing, and INR monitoring, if during these detection algorithms we're looking for how often are patients getting daily INR checks to enable the clinicians to detect earlier on instead of a severe episode of over-anticoagulation and bleeding, is that built into that particular EHR in that institution so they have clinical support. So, whenever you order Warfarin, the patient is getting daily INR checks. Are there protocols in place to allow the pharmacist to potentially order or can that be automaticallyy ordered into their system or something along those lines so that you don't have to wait for a pop up to show up?

That it just automatically is part of the treatment algorithm if you're going to have someone on anticoagulation that you're also monitoring. And that would also help if you have new physicians or physicians from institutions that do have that in place and they come to this new institution and no monitoring is in place. They're going to be at high risk for making an error whether they've relied on the system to help them care for patients in the past. So, I think there definitely are EHR usability lessons learned. And I think the national reporting systems, PSOs, and addressing potential gag clauses around sharing usability issues and best practices as well is a critical next step that can be addressed beyond just alerts, although they do have their time and place.

David McCallie - Individual - Public Member

Thanks. That's helpful.

Steven Lane - Sutter Health - Co-Chair

Yeah. I'd like to understand maybe from the ARC folks or any of you what are the current requirements for hospitals to report adverse drug events when they occur? Is this all voluntary and then, just this subsequent monitoring by ARC? Or do we actually – are we moving to a point where there's required reporting around this?

Noel Eldridge - AHRQ - Guest Speaker

This is Noel from ARC. I was off for about three minutes and then, I called back in about two minutes ago. So, I don't know if anything happened. Answering this question, I know nothing associated with ARC is mandatory reporting. You might check with the FDA to see how they perceive their reporting requirements. I'm not an expert on that. And then, there are some types of events that might be considered sentinel events that if the hospital is joint commission accredited, it wouldn't necessarily have to report it to the joint commission. But the way I understand the joint commission rules, they need to be able to show it to the inspector or the visitor from the joint commission when they come to the facility to say have you had any sentinel events in the last year. Show me what they were.

But I would check with FDA on what's mandatory in terms of reporting. The ARC programs are not mandatory and there's nothing mandatory at ARC to my knowledge.

Steven Lane - Sutter Health - Co-Chair

Because I think, to David's point, which was a really good one, clinicians are already being peppered with alerts all of the time. And if anything, I think the drive is to try to decrease those as opposed to look for new opportunities. But hospitals, presumably, are developing systems of having patient safety officers, having clinical pharmacists who are keeping an eye on medication usage and events. And it seems like some of those CDS type alerts could, rather than being directed back at the ordering provides, be directed at a patient safety officer or pharmacist who could have an opportunity to potentially intervene without directly impacting or primarily impacting the ordering providers or the administering nurses.

And that seems like a potential opportunity. But it seems, in the absence of any requirement to report on the part of the hospitals, it would be hard to incentivize those kinds of systems.

Arien Malec - Change Healthcare - Member

I'm, by the way, looking at the Med Watch page and adverse events for drugs outside of an IND context are voluntary. There is mandatory reporting for device-related deaths or serious injuries. So, it depends on the type of drug versus device and the context of use.

Steven Lane - Sutter Health - Co-Chair

Thanks, Arien. Well, we are at time. And I want to thank everybody for their participation. Our next task force meeting is in two weeks. We have made some outreaches to the FDA and to some representatives of the pharma industry. But we don't have clear commitments, I don't think, for two weeks out. We may. The co-chairs are going to be coming together. We may end up wanting to use the next meeting to fall back and spend time with the task force itself to digest and contemplate what we've heard over the past couple of meetings and start to put together some – see if there are recommendations that we can put together out of this. Any final comments from the task force? If not, thank you all for your time today and have a good rest of your day.