Interoperability and Patient Access Final Rule Call

Moderated by Nicole Cooney
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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. All lines will remain in a listen-only mode until the question-and-answer session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I will now turn the call over to Nicole Cooney. Thank you. You may begin.

Announcements & Introduction

Nicole Cooney: Hi, everyone. I'm Nicole Cooney from the Provider Communications Group here at CMS, and I'll be your moderator today. I'd like to welcome you to this Medicare Learning Network call on the Interoperability and Patient Access Final Rule.

On May 1st, CMS released the Interoperability and Patient Access Final Rule, listing ways to give patients better access to their health information. Using data exchange through secure Application Programming Interfaces or APIs, we took a first step in making health information more available to patients and moving toward greater interoperability across the health care system.

During today's presentation, we'll cover several implementation policies from the final rule. Before we get started, you received a link to the slide presentation in your confirmation e-mail. The presentation is available at the following URL, go.cms.gov/mlnevents. Again, that URL is go.cms.gov/mlnevents.

This call is open to everyone. If you're a member of the press, you're welcome to listen, but please don't ask questions during the Q&A session. Instead, send your inquiries to press@cms.hhs.gov.

We have several presenters today. Alex Mugge and Denise St. Clair are joining us from the Office of Burden Reduction and Health Informatics, and Scott Cooper from our Center for Clinical Standards and Quality. Alex will get us started.

Presentation

Alexandra Mugge: Thank you. And thank you to everyone for joining us here today to hear more about the CMS Interoperability and Patient Access Final Rule. We're looking forward to a very informative discussion today. My name is Alexandra Mugge, and I am the Director of the Health Informatics and Interoperability Group here at CMS. That group falls within the Office of Burden Reduction and Health Informatics. I also serve as the Deputy Chief Health Informatics Officer.

My team here at CMS oversees and supports the interoperability efforts across our agency. And this rule is one of our key achievements in the last year. If we can go to – if you can go to slide 2, that's the first slide after the intro, we have a picture of our journey map here. And this rule that you're going to hear about today, we believe marks the beginning of a data exchange landscape that will open new opportunities for all stakeholders.

The concept of interoperability has historically been thought of as an issue for EHR vendors and clinicians. But true interoperability cannot be limited to clinicians and EHR systems. It also includes payers, researchers,

innovators, and everyone in health care. It actually involves many of the stakeholders that we here at CMS regulate.

Our team in the Health Informatics and Interoperability Group is strategically placed within CMS to have an enterprise view of interoperability efforts going on throughout the agency, and to help promote certain key focus areas, including what you see here on this slide. The patient access, which is one of the areas where we spent a lot of focus on our interoperability rule and where you'll hear a lot more about that in just a moment. We also have an enhanced focus on connecting health care through data exchange, and a focus on technology and standards. These focuses combined together help us to set key focus areas for our quality programs, for our rules, and our policies that will help guide us to a more interoperability-focused landscape within the areas that we regulate.

All of this, as you can see on the bottom of the slide is built on a foundation of privacy and security. Because privacy and security are key for patients to trust in the system, and to be able to access their data securely, safely, and without special efforts.

Before we turn it over to Denise to cover some more details of the rule, I just wanted to emphasize some of the key areas that we have really focused on and some of our overarching thoughts on interoperability and why we have – or I guess the motivation of this rule. Interoperability is a journey. This is something that we say frequently when we're talking about this particular slide, in our landscape and our map to interoperability, is that this is really a journey and one that doesn't necessarily have a definitive endpoint. That doesn't mean that we won't get to interoperable data exchange.

That's not at all what we mean when we say that it's a journey. What we mean is that we will ultimately get to a point of interoperability where data is flowing freely and securely within our health care ecosystem. But our work to maintain that will never be done.

Technology and innovation is what makes our health care system great. It's part of what helps makes our health care system great. And technology is always evolving, which is why we must continue to evaluate new technology and update our policies to keep pace and help foster innovation in health care.

So now to talk a bit more about the intersection of policy and technology, I will turn it over to Denise St. Clair to give you more information about the CMS Interoperability and Patient Access Final Rule.

Denise St. Clair: Thanks so much, Alex, and thank you all for joining us today. We are excited to have an opportunity to talk through this rule with you in some detail. And we're going to spend most of our time today on slide 3 of our four-slide deck that you have available to you. I'm sure many of you have seen this slide once or more. And this is just a snapshot of all the policies in the rule.

And what we really want to do today is go through each one and work to answer the questions that we know you have. We have gotten a lot of questions as we've all begun to implement the policies in this rule. And so, as much as we can in one place at one time, we want to try and address those top-level questions. And, of course, we'll be looking to leave some time at the end for additional questions as well. But I'm just going to dive right in; we're going to start at the beginning and work our way through.

Public Reporting Policies

And so, the very first policy you see here is a series of two public reporting policies. The first is information blocking and public reporting. So, this policy applies to providers. And what this requires is that with the publication of data collected for the 2019 performance year, will publicly report an indicator for eligible clinicians, hospitals, and Critical Access Hospitals or CAHS that may be information blocking based on how they attested to certain program requirements.

So, we anticipated that these data may be available for public reporting in late 2020. And officially the rule says no earlier than late 2020, because it really does depend on when the 2019 performance year data are available for reporting. And I do not believe that's yet. So, it may be a little bit later than the earliest date.

And – but what will this mean, this will mean that information will be publicly reported on Physician Compare or now Care Compare for eligible clinicians and groups attesting under the Quality Payment Program promoting interoperability category. So, right now, when you begin your process of reporting, you're promoting interoperability category data, you start with a series of three attestations, those are the three information blocking attestations that issue here. So, based on responses to those attestations, you may indicate you – there's a possibility you are information blocking. If that is the case, then you're – that would be reported on your page on the Physician Compare website.

For hospitals, attesting under the Medicare fee-for-service promoting interoperability program, that information will be included on the CMS website as well. The information that's available for public reporting will be previewed at least 30 days prior to it being made public.

And so many of you are aware of the preview processes for, say, quality data, for clinicians and groups, so it'll be part of that process. And so, that is step one, is information blocking, public reporting, and this is an opportunity for some transparency for patients in particular as they look for providers to serve their needs and understand more how data are flowing throughout the health care system.

The second public reporting policy we have is regarding provider digital contact information. So, we require that we will publicly report the names of – and National Provider Identifier, NPI, numbers of those providers who do not have digital contact information included or updated in the National Plan and Provider Enumeration System, much better known as NPPES. So, we updated NPPES in June 2018 to capture one or more pieces of digital contact information. This could be a provider's direct address, or it could be a wide range of other digital endpoints such as your FHIR API endpoint.

But we do suspect that right now, starting in the phase we are now, that most providers will be putting their direct address in NPPES for the purposes of this policy. The goal here is really to support care coordination and electronic communication between providers. And a direct address is a secure method of communication that can really help support this. And then, obviously, as more and more application programming interfaces come online, and there's more opportunities for electronic exchange of information, the ability to add a number of different endpoints into NPPES will be amazingly helpful for care coordination and communication.

But we do – we will report those who don't have information in the next short while, available on NPPES to start this process off. And, again, you know, this is secure methods of communication and official endpoint, so

an e-mail wouldn't work. A direct address is different. So definitely making sure it's the right kind of endpoint that is included in NPPES and there is additional information on NPPES to help understand what an endpoint is.

We were originally targeting to publicly report these data at the end of 2020. We can tell you right now that we are targeting – officially reporting the list of names and NPIs that aren't currently including digital contact information by the end of the first quarter of 2021.

Now, there is a downloadable file that is currently available. So, all information about what is or isn't on NPPES is always available for public download. But one of the reasons that when you're giving a little bit more time to the public reporting of this specific list is because we're working on an enhancement that will allow for easier bulk updating of digital contact information on NPPES. So, we've heard from some of you about some challenges in the current process. And currently attempting to bulk update a whole roster of providers' information at once is more complicated than perhaps is most ideal. So that's something that the team is actively working on. And so, we will publicly report the list after that bulk update is made available for all of your use.

And what we really strongly encourage is that you keep a close eye on the NPPES main page, which is nppes.cms.hhs.gov. So that NPPES main page will continue to include more information, including when that bulk updating feature is enhanced, including our target public reporting date, and including some additional information about those provider types that are exempt from this public reporting.

Something we noted in the rule was that at a later date, we would make more information available about this. And so, again, going back to thinking about the goal of this policy of coordination of care and communication across care team, you can imagine that some of the provider types that would not be included might be a technician who is not actively engaged in care coordination activities. So, again, more information about that will be posted on the NPPES main page.

And one other point we will clarify, appreciating some of the questions we've gotten on this is that this is a focus on individual digital contact information versus organizational level, again, to facilitate that care coordination. Really the goal here is that communication between care teams.

And we will also note that both of these public reporting policies are completely separate from the Office of the National Coordinator, ONC's information blocking policies. And so, we did both release rules on May 1, CMS, the Interoperability and Patient Access Final Rule and ONC, the ONC 21st Century Cures Act Final Rule, and there's a ton of synergy between them. But this isn't one place. So, just to make sure folks are clear that these two policies are completely separate, and there are no implications across the rules for these public reporting policies. So, we just want to make that super clear.

So those are our first two policies on public reporting. We have public reporting information blocking attestations. And we have digital contact information in NPPES.

Application Programming Interface Policies

The next two policies that we're going to focus on are our two Application Programming Interface policies or our API policies. And these are definitely two things we are incredibly excited about as we continue to move toward greater interoperability and really leverage the technological advancements we have at our fingertips in health care that we've been leveraging across so many other sectors to improve care for patients, to get information flowing, to make sure the right information is at the right place at the right time to support care and patient outcomes.

So, the first Application Programming Interface we're requiring is the Patient Access API. And this policy applies to Medicare Advantage organizations, Medicaid and CHIP fee-for-service programs, Medicaid Managed Care Plans, CHIP managed care entities, and Qualified Health Plan issuers on the individual Federally Facilitated Exchanges. So, when we talk about impacted payers, that's who we're talking about here.

We finalize that this API would need to be applicable starting January 1, 2021. But we announced that we would be exercising six months of enforcement discretion when we released the rule on May 1st, officially in the Federal Register, although it was public a bit before that in March. But we noted on May 1 that we were exercising six months of enforcement discretion due to the public health emergency. So as a result, we will not enforce either the API finalized in this rule before July 2021. So, we are enforcing six months' enforcement discretion.

So, to start, what does the Patient Access API policy require? Well, it requires that impacted payers implement, test, and monitor a secure standard-based API. And the APIs in this role, and this is synergistic with ONC, we are both requiring FHIR release for APIs. And this standard-based FHIR API must be accessible to third-party applications and developers.

So, with the approval and at the direction of a current enrollee, payers must permit third-party apps to retrieve the enrollees' data via the Patient Access API. The API must meet the interoperability technical standards that are finalized by Health and Human Services, HHS, in the ONC 21st Century Cures Act Final Rule. And those are, of course, details in the rule itself. And the API must include a minimum set of data.

As always, the rule is the floor. This is the minimum you must include to be compliant. But, of course, you can always include more. But at a minimum, the policy requires that adjudicated claims including cost information, encounters with capitated providers, provider remittances, enrollee cost-sharing data, and clinical data as defined in the U.S. Core Data for Interoperability or the USCDI Version 1, if maintained by the payer, must be made available via the Patient Access API. So, again, that's adjudicated claims, including cost data, encounters, the USCDI clinical data, if maintained by the payer.

For Medicare Advantage organizations that have a prescription drug plan, they must also make available prescription drug claims as well as formulary information. And for Medicaid and CHIP fee-for-service and managed care plans, they must make available preferred drug list if applicable.

All data must be available no later than one business day. So, one business day after a claim is adjudicated or any counter is received. And payers need to make data they maintain with the data service on or after January

1, 2016, available. So, we're going to dig into all that a little bit more, but just want to make sure we cover the basics first of what is in the requirements.

So, in addition to requiring the sort of basic data that needs to be included and made available via the API, there are also some documentation requirements. So, this policy requires business and technical documentation necessary to interact with the API be made freely and publicly accessible. And, of course, the APIs must comply with all existing federal and state privacy and security rules and laws and all existing federal and state and local and tribal laws that apply.

So, this is a different way, a new way, we hope more efficient way to be able to share data with patients, but it doesn't change any of your obligations regarding what data can and can't be shared. So, for instance, sensitive data covered under 42 CFR Part 2 that must still be shared only under the existing rules and regulations. So, a very, very, very important point to continue to point out.

There is only one reason a payer can deny access to an app to the Patient Access API. And that is, if the entity reasonably determines that allowing an app to connect or remain connected would present an unacceptable level of risk to the security of the PHI on the organization system based on objective and verifiable criteria. So that is the only reason that a payer could deny access to an app.

Payers also need to make some educational materials available for patients. A payer needs to make available and an easily accessible location on its public website. Or through its normal end or through its normal communication channels and information on steps the individual may consider taking to help protect their privacy and security as they look to share their health information with an app of their choice. And payers must also include practical strategies to safeguard privacy and security, including how to submit a complaint to the Office of Civil Rights, OCR, if there's a concern around HIPAA, or concerns for the FTC around data with a third-party app.

Because the third-party apps, generally speaking, are not covered under HIPAA. These would, instead, be covered under the Federal Trade Commission. So, important to provide that information.

CMS, we have provided some content on our website. And the fourth slide of the deck that you have is the link to that website. And there's a ton of information on there. But one of the things on there is some content that you can use and tailor best to your patient population to support putting together the patient education materials.

So, that's the basics of what's required in the Patient Access API. But we really want to dig into some of the big questions that you have had about this as you really work to start implementing this rule. So, first things first, the Patient Access API applies to current enrollees. So, current enrollees include their personal representative. As stated in the final rule, whenever we say enrollee, we also mean personal representative.

So, according to HIPAA privacy regulations, a personal representative is someone who's authorized under state or other applicable law to act on behalf of the individual and making health care-related decisions. So, it could be a parent, a guardian, someone with medical power of attorney, these are all possible personal representatives.

So, just as if we're operating on paper, and patient has designated someone as a personal representative, and that personal representative could request information on the patient's behalf. The same could be true via the API. So, on the patient's behalf, they could find an app of choice and request the patient's data via the API.

The policies in the final rule require that a patient's action be addressed exactly in the same way, whether it's them or the personal representative. So, something to be aware of the data.

This is where we get a lot of the questions. So, first things first, claims in the encounter data. We said it's adjudicated claims that need to be made available via the API within one business day after adjudication. And that is any claim for payment decisions that may be appealed, were appealed, or in the process of appeal. And the clock starts once the claim is adjudicated, and that adjudicated claim is received by a payer or it's – after one business day after the accounted data are received by the payer.

So, what this does is it allows for potential delays in adjudication or delays in the providers submitting data to payers, or we appreciate that there's many different ways that this process works. And we appreciate that adjudication is, in fact, a process. So, we don't define adjudication in the rule. But according to both Medicare and Medicaid, the process – adjudication is the process of determining if a claim should be paid based on services rendered, the patient's covered benefits, and the provider's authority to render the services.

As such, we really do appreciate this is a process. And so, it really is up to the payer to look and assess your process, and then make the claims data available timely within one business day of your adjudication process being complete. So, again, we really ask that you look to your process and find that moment in adjudication, in that process, when that claim is ready to go and share that information timely.

To facilitate sharing data via the Patient Access API, we suggested a series of IGs, implementation guides, to support sharing data through HL7, and through FHIR-based API. We didn't require the use of these IGs, but we did strongly suggest that payers use them, and we did provide a link to those IGs. And, again, that link on that fourth slide of your presentation materials, that is the website with more information about all these implementation guides. And we strongly, strongly encourage you to take some time to look at that information if you haven't already. So that is an important piece.

So, for the claims and encounter data, we suggest that you use the HL7 CARIN IG for Blue Button. So, we again didn't require it. But we do strongly suggest it. Generally speaking, if a payer uses a suggested IG to share particular data and build the API to spec using that IG for that data, that API, technically speaking, will be compliant with the requirements for that data type. So, if you use the HL7 CARIN IG for Blue Button for claims and encounter data, you will know you're good. Assuming you do build the spec, you have covered your requirements for the data – for that data to be included in the API.

So, we did mention that the rule requires technical documentation to be made available. Well, another major benefit besides having this wonderful toolkit that has been created by an amazing community in a public open process through HL7, you also have the benefit if you use the suggested IGs to having a lot of that technical documentation already provided for you. So that will help you meet the technical documentation requirements of the rule as well.

The other thing is looking to the IGs will provide you with the specific data elements that you need to include with the necessary information about how to format and map these data to FHIR.

So, the IGs is really, really are an incredibly important and valuable resource for payers and for app developers. Because if the app developer knows exactly how you're formatting and making the data available, they'll be able to an incredibly innovative ways of bringing in those data into the app of a patient's choice and share them back with a patient in a way that can truly help them be better decision makers.

And we've seen this already through the CMS Blue Button 2.0 where we see, you know, apps that help patients manage their chronic conditions, for instance. And, you know, if I'm a patient with diabetes, then information from my claims and encounter data and my clinical data will be able to inform how I make decisions about my care and how I understand my care, and even remember when my care happens. So, these IGs are really, really wonderful resources for both the payers and the app developers.

But one important note here, the rule did not preclude the inclusion of vision and dental claims in the Patient Access API. However, as it turns out, at this time, the CARIN IG for Blue Button cannot fully accommodate vision and dental claims. This is something that is planned to be included in the next iteration of the implementation guide, which should be available in 2021. But, as a result, we appreciate that payers will not be able to share vision and dental claims using this IG through the Patient Access API to start.

And so, like we said, if you use the suggested API, or the suggested IG, then we do, technically speaking, consider the API to be compliant. So that would mean we appreciate this time, the vision and dental claims would not be available. Once the next iteration of the implementation guides are available, we'll provide information regarding when vision and dental claims should be ready to be shared via the API.

And, again, this won't be until the IG is updated and published, and payers have time to implement accordingly. And this is probably a good time to remind you all that there is a standard version update process included in the rule. And so that really helps us accommodate situations just like this.

We are all working together to get a new and innovative standard up and implemented the scale across the health care system. And so, we're going to learn some things as we go together here. But this advancement process really does help us address this.

So, what that says is that when a new version of a standard including an implementation guide is available, and that it seemed ready to go, that can be used, assuming it doesn't have any breaking changes. So, assuming using the new version doesn't prohibit anyone using the old version from continuing to share and receive data.

So, that will collectively help us all be more agile in this process. And so, that might be one of the first reasons we all have to engage that process.

Moving on to clinical data, as defined in the U.S. Core Data for Interoperability or the USCDI Version 1. And I'm sure at this point, you guys are all very much used to hearing about the USCDI at this point. But we know payers claim data, you've got that you're used to that. That's something you work with on every single day.

But the clinical data as defined in the USCDI was definitely something we've got a lot of questions about, and something we want to talk a little bit more about with you today. So, again, the rule states that impacted payers, Medicare Advantage, Medicaid and CHIP fee-for-service, Medicaid and CHIP managed care and Qualified Health Plan issuers on the Federally Facilitated Exchanges need to make the data, as defined in the USCDI, they maintain with the data service on or after January 1, 2016, available via the Patient Access API.

The first thing that we clarify a lot when we talk to folks about this policy is what does the rule define "maintain" to be. So, the rule defines maintain to mean, the payer has access to the data, control over the data, and the authority to make the data available through the API.

So, this includes information maintained on behalf of the payer by a contractor or third party. And it really is up to the payer to evaluate your system and to understand how data are maintained in your system for each enrollee. And based on this definition and, obviously, in good faith, makes the data available for sharing through the API.

So, as payers have been working to assess their systems and begin the work of implementation of the policies in this rule, and specifically the Patient Access API, a number of payers have reached out to ask how to address situations where a payer maintains unstructured data, such as a really large PDF, or a scan of a fax, that may or may not include data elements in the USCDI.

So, again, we say, let's go back and remember the goal of this work. The goal is to get patients data in a format they can use, that adds value, that helps them be informed decision makers. That means an absolutely giant PDF – absolutely giant PDF may not help. And it definitely will not help us get standardized data elements flowing in a way that apps can really innovatively use and get these data back to patients in a truly usable format.

So, how do we address this? Well, what we know is that payers should focus on the USCDI data elements that can be identified as a data element level. So, data that a payer maintains as part of an enrollee's records as a discrete data elements that the payer can then map the FHIR and make available via the Patient Access API. Of course, we strongly encourage payers to work to make as much data available to patients via the API as possible to ensure patients have access to their data in a way that will be most valuable and meaningful to them.

But we are not asking payers to manually go through gigantic files that cannot be parsed into data elements efficiently for the purpose of this API. And we are not asking payers to share these unstructured files that may or may not have USCDI data elements in them. So, that is an answer to a big question on unstructured data.

Another important note about clinical data is that the rule does not limit the available data by how the data are being used today, or the purpose for which the data were received by the payer. So, if the data are currently maintained, and at the data element level, they must be made available via the Patient Access API if they are a bit data element as defined in the USCDI. However, again, it's up to the payer to assess their system and in good faith work to get valuable data to patients.

So, one type of data that has come up in questions we've gotten before has been around at HEDIS measure data. So, a payer may have isolated certain clinical data elements from a patient's record to support submitting HEDIS measures.

But the actual measure data submitted may be some combination of information that is not actually the best information to share with the patient. So, an example, blood pressure readings. You – the actual data you submit for your HEDIS measure may be a combination of the best systolic and diastolic readings for a given patient, but not actually a valid current reading of those blood pressure values for the patient. So, it might be a somewhat nonsensical, combined numbers.

And so that would, of course, not add value for the patient. But the source information for those two best readings would be. So, if you pulled two different readings, and then combined the best systolic and diastolic, you know, the original readings, the source information you're pulling from, if those are identified at the data element level within the enrollee's record, then yes, those would be available to share. And those would be wonderful data to make available for patients.

In this way, you have, for the purposes of calculating your HEDIS measures, you may have data available via the Patient Access API, to share via Patient Access API. So, again, we really suggest, looking at your system, looking at your data, appreciating the goal of the requirement, and then really working as best you can to make the best most valuable data available to patients within one business day. So, that, I think it's the real crux of most of the questions we've gotten around the clinical data.

Again, we strongly suggest using certain AP – or IGs, implementation guides, to support making this data available. And I believe that we may or may not have a URL issue on the slides that we sent you. If we do, we'll fix it. So, don't worry about that. We'll get you that information if it isn't available.

And for the USCDI clinical data, we originally suggested using the HL7 U.S. Core IG to support making these USCDI data elements available via the Patient Access API. But, again, we're all learning together. So, as folks started implementing, we thought we received some information from some payers who reached out and asked that we also consider using the HL7 Da Vinci Payer Data Exchange or PDex IG for these data.

And, ultimately, either of these IGs, the US Core IG or the PDex IG, is sufficient to satisfy the data requirements for the USCDI data for the Patient Access API. So, you could use either/or. The PDex IG is based on the US Core IG, but there's also some additional information which is really designed for payer-related use cases. So, we have more information about this on the website, but there are some additions including a medication dispense resource. There's a device resource, there's a more payer-specific provenance resource available.

So, these are the reasons that the payer community requested that we consider. I'm also suggesting the PDex IG, and we did, so that either of those two IGs can be leveraged to meet the requirements there.

So, we talked about claims data, we talked about USCDI data. There's also formulary data that must be made available via the Patient Access API. And again, for MA organizations that have a prescription drug benefit, formulary data must be made available, and for Medicaid and CHIP fee-for-service and managed care preferred drug list must be made available, if applicable.

So, we will note that this should be current relevant information. We don't need to share historic formulary data dating back to 2016. As, again, the goal here is to help in current patient decision making. And we do strongly suggest that you use the HL7 Da Vinci Payer Data Exchange or PDex formulary implementation guide for these data. We do understand that there's multiple use cases for the formulary data per the formulary IG.

The rule doesn't prohibit making the formulary data openly available. So that's one of the use cases, as much as, you know, we'll talk about the provider directory data making the formulary data completely openly public so it can be used for shopping purposes. So that's as, in this case, where you may have data for the next plan year available. And as people are shopping for plans, they could shop based on formulary information.

So that is a completely allowable use case, should it be something that you as a payer want to engage in. That's not the use case required by the rule. But, again, it's not prohibited. So, you're absolutely and totally and wonderfully permitted to do that.

The final rule requires that the formulary data specific to the patient in question be made available via the Patient Access API. So, as a result, you are sharing with the app. So, again, a patient finds an app of choice, they sign up, they consent, they provide their payer information, they say I want you to get my data from my payer. That app then pings the payer's API.

And at that point, you are sharing some PHI, you are sharing personal health information in terms of the claims and the clinical data. What we ask is that you also share the formulary data which, of course, doesn't need to be authenticated because it is publicly available data. But we do ask that you share it along with the data that is necessary to authenticate, to facilitate getting all of this data to the app of the patient's choice for their use.

OK. So, a few other things we want to be sure to discuss with you about the API requirements in this rule, because we get a lot of questions on this. Testing. Testing the API. So, there are reference implementations and testing tools available on the site, the website provided where the IGs live as well. And we strongly, strongly encourage you to use these resources. They're wonderful resources to help you start to make sure your APIs are doing what they need to be doing. And we can't recommend enough getting engaged in the HL7 community, the workgroups. This is all an open community.

And so, being involved in this process, appreciating more and more data are going to be made available through the wonderful work that HL7 and all the amazing accelerators are doing to make more and more implementation guides available for use.

So, given this, we can't encourage enough folks getting involved in that process. Connectathon are an absolutely wonderful opportunity to test your APIs and to interact directly with the authors and the technical experts of each implementation guide. You can get your questions answered, you can work with peers, it's an absolutely wonderful opportunity. So, we really can't suggest enough.

Look at the testing and reference implementation materials made available. Get engaged with the HL7 community. Get onto it. These are wonderful, wonderful ways to get more information as you work to implement.

Another thing we hear a lot about is we get questions about vetting. And I'm air quoting vetting here of third-party apps. And, again, I say, as finalized, the rule states that a payer may only deny or discontinue a third-party applications connection to their API if the payer reasonably determines consistent with a security analysis under – I'm going to be specific – 45 CFR Part 164 Subpart C. Now, that is your current security analysis obligations for your systems under HIPAA today. So that does apply here as well.

That based on your determination, consistent with that analysis, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk. And that's the only reason that you could deny an app access.

The criteria and process for assessing access, again, is consistent with the current HIPAA security rules. And the current work covered entities are doing to perform risk analysis of your management systems, the measure process, and your data tools today.

And so, that should be a known thing. That said, you know, we can't stress enough, Alex, mentioned at the start, we believe that patient privacy and security are absolutely vital. And, as a result, in the final rule, we did also provide an option for payers to ask a third-party vendor to attest to certain privacy policy provisions being in place.

So, if you choose, as a payer, you can ask that apps attest to having certain privacy provisions in place. And we detail what, you know, some of those things could be in the rule itself.

For instance, making sure that there is a truly publicly available, easy to find written in plain language accessible privacy policy, that patients can really engage with prior to choosing to share their data with an app. Providing information in that privacy policy about secondary uses of data, about how to discontinue access to your data from the app, if you so choose. About what other information on a patient's device the app might access – their location, for instance.

So, all of this information, these are things you can ask an app to attest to. Now, the app doesn't have to respond. And if they don't, or if they attest in such a way to indicate they may not have these provisions in place, the payer has the ability to inform the patient of that. And at that time, the patient could say, that's OK, please share my data anyway. And that would be what would be necessary, given the patient has already consented and requested their data to be shared, and it is their data to share. Or they may say, you know what, never mind, I'm going to go ahead and look for a different app.

So, that privacy policy attestation option that's in the final rule does provides another opportunity to support patients as they choose apps of their choice to use to support their decision making and to engage in their health care. We point out a couple of wonderful resources in the rule to support with the Patient Access API privacy policy attestation. In particular, we call out the CARIN Alliances code of conduct. We call out ONC's privacy, model privacy notice. So, these are some wonderful resources that you can start with.

We also say look to the solutions industry is making available around this and to, you know, to really kind of coalesce around apps that are making this information really transparent, and are, you know, really building to these privacy and security considerations. So, there's a lot going on in this space and we're excited to see the

additional innovation that all of you in industry will bring to this. But do appreciate that without question privacy and security is absolutely paramount. And these are some additional ways to take that into consideration.

So, I know I spent a ton of time on that, but we have gotten a lot of questions. And we really wanted to make sure to cover as much of them as we could. And all of that technical detail around the APIs applies as well to the second API policy, which is the Provider Directory API. The Provider Directory API applies to the same group of payers except for one. It applies to Medicare Advantage organizations, Medicaid and CHIP fee-for-service programs, Medicaid Managed Care plans, and CHIP managed care entities.

It does not apply to Qualified Health Plan issuers, given existing requirements to make provider directory information available in a machine-readable format. Again, this was finalized as applicable starting January 1, 2021. But we are – we announced again, as mentioned earlier, that we were enforcing six months of enforcement discretion due to the public health emergency. So just like the Patient Access API, we are not enforcing the Provider Directory API before July 1, 2021.

Impacted payers are required to make a complete and accurate set of information about their provider networks available via this Provider Directory API. The API must be public facing, so it has to be available to a public facing digital endpoint on the payer's website so that it can be easily accessed by a third-party app and easily discoverable. At an absolute minimum, the provider directory must include a provider's name, address, phone number, and specialty.

And as noted in the regulation, there are some additional data elements required for certain programs. So, for instance, for Medicaid, appreciating some of your current requirements around provider directories, there are additional data elements required, and those are again detailed via the rule. For Medicare Advantage plans with a prescription drug benefit, they must also make pharmacy directory information available through the API.

And that includes at a minimum, pharmacy name, address, phone number, and the number of pharmacies in the network or the mix. The types of pharmacies that are included, so is it a retail pharmacy, is it a compound pharmacy, et cetera. We do note that contracted pharmacies are required to be included in the Provider Directory API for MAPD plans.

And like I said, all the same technical requirements apply to the same technical standards as finalized by ONC are required except because this information is already publicly available and there is no personally identifiable information.

The security protocols related to authentication and authorization do not apply because it is completely truly publicly available information. Civil does require that the information available through the API be updated no later than 30 calendar days after an update is received or new information is received by the payer.

And we do note that we strongly, strongly suggest you use the HL7 Da Vinci PDex Plan Net IG to meet this requirement. Again, suggested, not required, but strongly suggested. And we do point out that in August, there was a Medicaid state director letter issued that indicated use of the Plan Net IG would make states eligible for certain types of funding. So, another motivation to consider using the Plan Net IG for this.

So, I am going to stop talking for a few minutes and pass things over to Scott Cooper to cover the next policy on the list, the patient event notifications, Conditions of Participation.

Nicole Cooney: Hey, Denise and Scott, this is Nicole. I'm sorry, I just want to jump in real quick because I think the URL issue that Denise mentioned was actually my fault at the top of the call when I read the URL for where you could find the presentation, I missed a key piece. So, let me say it again. And this is correct. I have checked it myself. It's go.cms.gov/mln hyphen or dash events. Again, that's go.cms.gov/mln-events.

The dash is the part that I was missing. Again, it's a dash in between mln and events. There's a list of all of our events there you'll find today's call, it's the second one on the list under event materials. There's hyperlinked word presentation, that's where the slides are posted.

And, again, we are going to have a transcript of this event. I know a lot of information has been covered. And we will be posting the transcript the same place where you're finding the presentation today. And with that, sorry, Scott, I'm going to turn it over to you.

Conditions of Participation

Scott Cooper: That's OK, Nicole. Thank you, and thank you, Denise.

I want to point out as you're all aware, the rule we've been discussing, the CMS wide interoperability rule, contain provisions that are revising the current Conditions of Participation, CoPs. That will, and this will be as of April 30th, 2021, applicability date for this part of the rule require Medicare and Medicare participating hospital – Medicaid participating hospitals, which includes short-term acute care hospitals, long-term care hospitals or LTCHs.

Rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals. And then also the CoPs that will – revising CoPs for Critical Access Hospitals or as they're known as CAHs, for them to send electronic patient event notifications to either another health care facility or post-acute care services provider or to a community practitioner.

And this would occur at the various points in the patient's hospital or CAH journey. It would be with the patient's registration and the hospital's emergency department. Admission to the hospital's inpatient services, whether that is from directly to the inpatient services or through the emergency department, the discharge or transfer from the hospital's emergency department, and then the patient's discharge or transfer from the hospital's inpatient services.

Most importantly, what I want to point out here is that the new requirements are going to be limited to only those Medicare and Medicaid participating hospitals in CAHs that possess electronic health record systems with the technical capacity to generate information for an electronic patient event notification.

And with that, I've kind of just briefly like to go over the high points of the regulations that this occurs for the hospital CoPs under medical records, CoP at 42 CFR 42.24. Also, the medical records and clinical records for Critical Access Hospitals and their separate CoPs under 42 CFR 45, as well as – since generally psychiatric hospitals fall under the hospital CoPs.

They have some additional special requirements, and they have their own medical records, clinical records requirements. So, the regulations are under there also. They're – other than specifying hospital, psychiatric hospital or CAH, they're all the same. To starting with just pointing out, again, with that, the – that it really only applies to those hospitals that have – that are utilizing a medical record system electronic or other electronic administrative system that is conformant with the content exchange standard at 45 CFR 170. 205 D2.

With that, it must be fully operational. The hospital has to demonstrate this. They will send notifications that have to at least include the patient name, treating practitioner, name, and the sending institution name to the extent permissible under applicable federal and state laws and regulations and not inconsistent with the patient's express privacy preferences. The system either sends these notifications directly, the hospital system, or through an intermediary such as an HIE that facilitates the exchange of health information. And as I pointed out earlier, this occurs at those various points involving the emergency department inpatient services, and then discharge or transfer from those parts of the hospital.

Along with this, the hospital or the CAH has to ensure that it sends its notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners that we list in the requirements, practitioners and entities which need to receive notification of the patient's status for treatment care coordination or quality improvement purposes. Those would be the patient's established primary care practitioner.

The patient's established primary practitioner group or entity, and/or another practitioner or other practice group or entity that the patient identifies as the practitioner or group or entity that is primarily responsible for the patient's care.

With that, I will turn it back to Denise. Thank you.

Payer-to-Payer Data Exchange

Denise St. Clair: Thank you so much, Scott.

So, we are continuing our journey through our patient – or Interoperability and Patient Access Final Rule snapshot slide. So, we just got through the hospital event notifications, which are applicable officially. I believe the exact date is April 30th as those become effective one year after the official publication of the rule on May 1st in the Federal Register.

And that takes us to the next policy, the payer-to-payer data exchange, which as you can see on this roadmap becomes applicable January 1st, 2022. And the date of that – that effective date does not change. And, so, we are still tracking to the payer-to-payer data exchange being applicable starting January 1, 2022.

So, what does the payer-to-payer data exchange require? This requires that impacted payers – and again, same but different list. So, the payer-to-payer data exchange applies specifically to Medicare Advantage organizations, Medicaid and CHIP Managed Care and Qualified Health Plans on the Federally Facilitated Exchanges.

The payer-to-payer data exchange in this first year of interoperability policy does not apply to Medicaid and CHIP fee-for-service. Of course, we always encourage folks to do what they can, but it is not required of Medicaid and CHIP fee-for-service in this first year. And as noted, they'll be applicable January 1, 2022.

This data exchange does not require the use of an API. But we did strongly encourage in the rule and we do continue to strongly encourage considering an API solution, considering what this policy does require is that to support a coordinated care between payers, that impacted payers exchange at a minimum data elements as defined in the U.S. Core Data for Interoperability, the USCDI Version 1, at a patient's request with another payer. And that the receiving payer incorporate that information into the plan's records about the enrollee.

So, you're already preparing and sharing USCDI data elements with third-party apps that the patient chooses via the Patient Access API. And now this policy is saying take those same data elements and make them available to exchange with a payer if a patient requests that their data be sent to another payer. So, we mentioned the Patient Access API is applicable to only current enrollees.

The payer-to-payer data exchange is applicable to current enrollees, and former enrollees up to five years after disenrollment. So, up to five years after an enrollee leaves their current plan, they can request of their previous payers to send data to another payer. And, so, a payer would be required to receive USCDI data from another payer that covered their current enrollee within the preceding five years. They'd be required to send USCDI data for any enrollee during coverage and up to five years after the coverage ends.

And they will be required to send data received from another payer under this payer-to-payer API data exchange in the electronic form or format it was received. So, if you receive data for a new enrollee, from say, you are a Medicare Advantage plan and you have a new enrollee, and a new enrollee was previously enrolled in a Qualified Health Plan on the individual Federally Facilitated Exchanges.

They could ask their QHP issuer to share with you their USCDI data. And if they share those data with you via an API, and you both have a Patient Access API, so you may have the tools available to receive it, then that becomes part of the data you maintain for the patient. And because you receive it via an API, you would easily be able to share it via an API, so you could do so.

If you received those data in another electronic format, you would not be required under this proposal to transform those data to FHIR and make them available. So, you're required to make the data available in the form or format it was received – electronic format, format, once it's been received under this policy. And again, payers needs to make data they maintain with a data service on or after January 1, 2016, available for the payer-to-payer data exchange. This is, again, consistent with the policy under the Provider Access API.

But important again to remember that this policy does not yet require a FHIR-based API, but we do, of course, strongly recommend. So, at this time, this is USCDI data only. It is current and former enrollees. And it's, of course, also patient directed. So, the patient would have to ask you to send the data and tell you who to send it to.

A big question we get here, and this also relates to the Patient Access API, is about what a lot of folks refer to as a quote, unquote "look-back period". So, it's appreciating that upon approval and direction of the enrollee, a

payer has to make the data that they maintain with a data service on or after January 2016 available. So, we want to, again, remember what the ultimate goal of this policy is.

Payers are in a phenomenally unique position to have a truly holistic view of their patients. A payer will see through their claims data and other interactions with the patient's care team the universe of – or providers within their network that are interacting with the patient. A patient can have a countless number of providers that they work with throughout the year, but generally have one to two payers. So as such, this policy helps the payer be the keeper of the longitudinal record for the patient and help that data move with the patient as they move throughout the health care system from payer to payer and provider to provider.

So, what we're ultimately looking for here is getting to a long-term goal of a patient having access to their complete electronic records that can move with them as they move throughout the system. So, this is our step one. And that is the decision to not go all the way back to the beginning of time when you first had a patient enroll, but to start with the data at January 1, 2016, forward.

So, if a patient asks for their data to be shared with a third-party app in 2035, and they have been with the plan since 2016, the plan must make all specified data with the data service on or after January 1, 2016, available. And that's true for both the Patient Access API and the payer-to-payer API. And, again, that's both will facilitate the creation and maintenance of this cumulative health record that can move with the patient as they move throughout the ecosystem.

So, we do note that this is specific to the data required within the rules. So, for the payer-to-payer APIs, USCDI data elements, for the Patient Access API, its claims encounter – claims and encounter data in the USCDI data. We do appreciate that for payers that is different than some of your current data maintenance rules. And that's something to account for. It's not their entire record, it is the FHIR-enabled data elements specific to these policies. But those data do have to be made available from 2016 forward while the patient meets the criteria of the policy.

So, for Patient Access API, it is in fact for current enrollees only. For the payer-to-payer data exchange, it's current enrollees, and then up to five years after disenrollment. So that has zero impact on current data retention policies for former enrollees, as five years is less time than what is currently required across programs. So, that is definitely a question we get and something we wanted to make clear that that is not a rolling period, that is the date moving forward.

Now, we do appreciate that enrollees can move in and out of plans. And, again, this comes down to how does the payer maintain data. So, if a payer – if a patient is with you and, say, a Medicaid Managed Care plan, from 2025 to 2030, and then they leave, and they go to another plan for 2030 to 2035, and they come back to you in 2036. Well, when they left you, and – they left you – it may sound so dramatic.

When they switched plan, that first time and 2030, if you basically close out that enrollment, and they are now no longer, you know, a current enrollee in your system, and when they re-enroll in 2036, it starts a new enrollment record, then that's a new enrollee and you have data for them from 2036 forward. And if you maintain their data from their previous enrollment, and they consider that part of their current enrollee records, well, then that's part of the current enrollee record and anything available from 2016 on would be available via

the Patient Access API. So, again, it comes down to assessing your system, further requirements in the rule, and proceeding accordingly.

Improved Benefits Coordination

We have one more policy that we required in this rule as a last on our list on this slide, and that is improving the dual eligible experience. And this is a policy that would become effective April 1st, 2022. And this policy requires that states participate in daily exchange of buy-in data to CMS. So, buy-in data indicates who is enrolled in Medicare and which parties are liable for paying that beneficiaries' Part A and Part B premiums.

So, the requirement is that those data now be made available for daily exchange versus the current – not daily exchange – by April 1, 2022. It also requires that states submit the required MMA file to CMS on a daily basis. So, the MMA file contains data identifying all dually eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries. So daily news every business day, but if there's no new transaction on a given day, then there's no available data to transmit. So, data would not need to be submitted on that day.

There are federal matching funds available to support implementation of these daily data exchange policies. And our dual eligible team is available for technical assistance with the states to support this as this comes online.

And so, that concludes our very in-depth overview of the policies in the Interoperability and Patient Access Final Rule. We hope we have pre-empted and answered a lot of the questions that we are very happy to get from you. And as we're always happy to work to support you and implementation of these important policies.

And I'm going to go ahead and kick it back to Nicole to open us up for some Q&A.

Question & Answer Session

Nicole Cooney: Thank you, Denise. We're now ready to take your questions. As a reminder, the event is being recorded and transcribed. And in an effort to take as many questions as possible, we ask that each caller stick to just one question. Please be mindful of the time that you take asking your question. We've got a lot of folks on the line. And, you know, just a little bit of time here for questions. So, I'll be monitoring things and moving on when needed to ensure that we get to as many callers as we can.

OK, Blair, we're ready to take our first question.

Operator: To ask a question, press "star" followed by the number "1" on your touchtone phone. To remove yourself from the queue, press the "pound" key. Remember to pick up your handset before asking your question to assure clarity. Once your line is open, state your name and organization.

Please note your line will remain open during the time you're asking your question. So, anything you say, or any background noise will be heard in the conference. If you have more than one question, press "star," "1" to get back in the queue and we will address additional questions if time permits.

Please hold while we compile the Q&A roster. Please hold while we compile the Q&A roster.

The first question will come from the line of Joseph Kunisch.

Joseph Kunisch: Yes, good afternoon, and thank you for this presentation. This is Joe Kunisch from Memorial Hermann Health System. My one question is, could you speak a little bit to how you're going to enforce compliance for both the payer side and then also on the provider side if there's a complaint filed on information blocking?

Denise St. Clair: So, this is Denise St. Clair. I can say that compliance really is part of the program requirements for payers. So, there are current compliance processes and procedures for each Medicaid, Medicare, Medicare Advantage, Medicaid CHIP, and the Qualified Health Plan. So as part of that compliance process, compliance with these policies will be folded in.

So, there will be more information about that as that comes through from each of the programs. So, it's not distinct from that current process. And it will be obviously program specific.

And, again, pointing out that in terms of information blocking for the purposes of the policies in this rule, the two – you know, the attestation on information blocking per the public reporting for that – for participation – for the Quality Payment Programs and the Promoting Interoperability Programs, that is simply a public reporting if information is attested to in such a way that may indicate information blocking, but that's that.

And in terms of questions around the Office of the National Coordinator, 21st Century Cures Act Final Rule, and information blocking, we strongly encourage you to reach out to ONC. They have an amazing website, with lots of information about the rule and opportunities to ask questions about the information blocking policies. So, we definitely suggest reaching out to ONC for that information.

Operator: The next question will come from the line of Dylan Lynch.

Dylan Lynch: Hello, good afternoon. Thank you for this presentation. My name is Dylan Lynch, I'm with Kaiser Permanente. We have a question. CMS for Blue Button 2.0, it required third-party apps registered with CMS before they were allowed to access Blue Button, including our testing tool and certain requirements. Are health plans expected to be the same with third-party apps, attempting to access member data, and if so, what are the health plan responsibilities in this regard?

Denise St. Clair: In this regard, per the rule, following the technical requirements as outlined in the rule will provide you with the information you need to ensure that the payer is doing what the payer needs to allow the app to access.

So, there isn't a, you know, there aren't grander requirements around – obviously, there are certain handshakes, and I'm trying not to use the word registered because I know that that can confuse folks who are not familiar with exactly how the API process works. So, it sounds like it's a much more dramatic process than it is.

So, for all the technical people in the room, excuse me for purposely working to be not technical. But, obviously, there are necessary handshakes that need to happen, necessary authentication and verification of who is connecting, why the security of that connection, et cetera.

And so, following the technical requirements as laid out in the rule, we'll provide you with the blueprint to do that. But beyond that, there isn't a need, you know, you don't need to have a development – developer sandbox, you don't need to have that additional – or additional resources available.

So, hopefully, that helps answer your question.

Dylan Lynch: Thank you.

Operator: The next question will come from the line of Ben Hanley.

Ben Hanley: Hi, thank you for the presentation. I have a question about the ADT notifications part of the final rule, and specifically about the observation care setting. I work with the New York eHealth Collaborative and we coordinate the Health Information Exchange System in New York State. And, you know, we've been reviewing our practices to make sure that we're complying with the rule in terms of different event triggers that would lead to notifications.

And, you know, after reading through the rule many times, I think there's still just a little lack of understanding how observation is meant to fit into the rule and if it's fully covered or not. And I think the most specific question I'd like that of Scott would be a scenario where someone comes in through an emergency room and is then moved to the observation – to an observation stay. Is a notification required at that point when they go from emergency to observation?

Denise St. Clair: Kiana or Danielle?

Kiana Banks: Hi.

Danielle Adams: Hi, this is – yes. Go ahead, Kiana.

Kiana Banks: This is Kiana Banks. Captain Cooper actually had to leave the call. However, I just want to say that the guidance for – the regulatory guidance for the CoP provisions that were discussed is still under development and has not been released yet. We so are working through some of the specifics of how some of this will be implemented. So, I don't know that, specifically, we're in a place to address that specific question.

But if you want to e-mail that to us, it would be helpful, so that we can make sure that we're taking that into consideration while we develop the guidance. But I'll give Danielle Adams an opportunity to speak on that as well in the event that she has something else to add.

Ben Hanley: Thank you.

Danielle Adams: No, that's what I was going to say. So, thank you Kiana.

Ben Hanley: OK, and who would I send that e-mail to?

Kiana Banks: You may send – go ahead.

Denise St. Clair: I was going to say all – it's Denise. I was going to say on the URL on the fourth slide of the available deck. On that page, there is a resource mailbox for the Health Information or Interoperability Groups, HIIG, that's us. And we can help shepherd your questions to the appropriate subject matter experts. So, if you e-mail your question there, we can make sure that the Conditions of Participation team get that question.

Ben Hanley: That's great. Thank you. I appreciate that. And is there an update on when those CoP guidelines will be released?

Danielle Adams: The guidance is – this is Danielle Adams. That guidance is working through our clearance process at this time, so we don't have a definite date. We would expect – hopefully, we're anticipating trying to get it out by spring, but we wouldn't necessarily have a firm date on that yet.

Ben Hanley: Oh, I see. OK, thank you, everyone.

Operator: The next question will come from line of Roxanne Barrera.

Roxanne Barrera: Hello, this is Roxanne Barrera. I wanted to ask a question about event notifications, especially regarding patients who are like per se south in Florida and then their providers are way up in New York, or the homeless population and/or patients who don't have providers designated.

Kiana Banks: Hi, this is Kiana Banks. So, is your question whether or not those long-distance providers will be required to comply with the requirements?

Roxanne Barrera: Right, just getting it there, like, across multiple states, right. They're only, you know, in a different state for, you know, vacation or residing down there. But their actual primary is multiple states away. Or if there are a lot of patients who don't have a designated primary provider.

Kiana Banks: So, our Conditions of Participation aren't limited by you know, the location of, you know, one particular practitioner. So, for example, if the patient is seen in a hospital in one state and the hospital meets the requirements, you know, the technical requirements for the notification provision and has a system that meets the technical specifications then that hospital is required to comply with the provision. And so, we would expect that, you know, measures would be taken by the facilities to make sure that they're complying with those requirements.

Danielle Adams: And this is Danielle. And on the part about the homeless individuals or those that do not have primary care providers, we – you know, the regulation does require to make a reasonable attempt. If there are – we would expect that if a hospital has made a reasonable attempt but there isn't an entity to send that to if there has been no development of a primary care relationship through the course of their hospital stay, that there would at least be documentation as to why that may not have been completed. So there at least has to be the attempt to do that.

Roxanne Barrera: OK, thank you.

Nicole Cooney: Well, I could take one more question, I think.

Operator: Our next question will come from the line of Lauren Ben Lynch

Lauren Ben Lynch: Hi, thanks so much for this presentation. That's been very helpful. I have a question with regards to the Patient Access API. How should payers authenticate or verify personal representatives of individuals? And kind of as a subset of that, how do you envision providing access under the Patient Access API to minors if at all?

Denise St. Clair: So, that's a great question. This is Denise. Regarding personal representative and privacy arrangements within enrollment groups, it's really important to again, realize that existing federal, state, local, and tribal law apply, and existing policies and procedures apply.

So, regarding a personal representative, if a current enrollee has designated a personal representative to be able to act on their behalf for their interactions with you, the payer, then just as you would authenticate and authorize that personal representative to engage with you in other ways, you would then have that information to engage with them via the Patient Access API.

So, authentication and authorization is specifically discussed within the technical requirements of the API. And so, for instance, there are some payers who may often complete the authentication process by pinging against credentials that they have for the patient that they use, say, for their portal. And so, just as the personal representative would have access to that portal, they would have access to the Patient Access API.

So, whatever you're doing today to authenticate the personal representative to be able to act on behalf of the patient in other capacities, and your interactions, that would be extended to the API, much in exactly the same way. So that's the anticipation there.

Regarding enrollment groups, it really does get specific to certain state requirements and a lot of situations, so we strongly suggest evaluating the different state requirements on this issue. But it is, again, consistent with your current practices and policies.

So, for instance, there's a number of states that have very specific requirements around adult dependents to be a part of an enrollment group, where they can dictate who – you know, even if they are a dependent as an adult in a QHP, they can dictate whether or not the head of the enrollment group say their parent or guardian can see their records.

There are a number of various considerations for minors and various different situations based on existing law. So, all of those existing relationships and legal responsibilities remain in place with the API.

So, at this time, if you're only able to share other paper or electronic records with certain members of minors' personal team or guardians based on different relationships, that would remain true through the API. So, it's just carrying the existing privacy relationships through to the API.

Additional Information

Nicole Cooney: Unfortunately, we've reached the end of our time today, and that's all the questions that we can take. After today's call, you'll receive an e-mail with a link to evaluate the call, and we hope that you'll take

a few moments to tell us about your experience. An audio recording and transcript will be available in about seven business days at go.cms.gov/mln-events.

Again, my name is Nicole Cooney. I'd like to thank our presenters. And also thank all of you for participating in today's Medicare Learning Network event on the Interoperability and Patient Access Final Rule. Have a great day everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect. Presenters, please hold.