Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information Proposed Rule Listening Session

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 participants will remain in a listen-only mode until the feedback session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect. I will now turn the call over to Nicole Cooney. Thank you. You may begin.

Announcements & Introduction

Nicole Cooney: Thank you. Hi everyone. I'm Nicole Cooney from the Provider Communications Group here at CMS, and I'll be your moderator today. I would like to welcome you to this Medicare Learning Network Listening Session on the Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information Proposed Rule. On December 10th, CMS released the proposed rule. Moving on, the CMS Interoperability and Patient Access final rule that would require certain CMS-regulated payers to improve the electronic exchange of health care data via application program interfaces and streamline the prior authorization process to reduce burden on payers, providers, and patients.

During today's session, CMS experts will briefly cover provisions from the proposed rule and address your clarifying questions to help you formulate your written comments for formal submission. Before we get started, you received a link to the presentation in your confirmation email. The presentation is also available at the following URL: go.cms.gov/npc. Again, that URL, go.cms.gov/npc. This call is open to everyone. If you are a member of the press, you are welcome to listen, but please refrain from asking questions during the feedback portion of the call. Instead, send your inquiries to press press@cms.hhs.gov.

At this time, I'd like to turn the call over to our presenters, Denise St. Clair and Lorraine Doo from our Office of Burden Reduction and Health Informatics. Denise?

Presentation

Denise St. Clair: Thank you so much, Nicole. Hi, my name is Denise St. Clair, and I am with the Health Informatics and Interoperability Group affectionately known as high IG in the Office of Burden Reduction, Health Informatics, and I am joined here today by my colleague Lorraine Doo. And we are going to take an opportunity to walk through the proposals and the rule that was released recently and is out for comment through January 4th. Comments are due on January 4th. So, we wanted to provide this opportunity to get a high-level overview and present you with an opportunity to provide some feedback.

So, who are we regulating in this proposed rule? Specifically, this proposed rule is regulating Medicaid and CHIP fee-for-service programs, Medicaid and CHIP managed care, and Qualified Health Plan issuers on the individually Federally Facilitated Exchanges. As we will discuss often, a number of the policies in this rule are building off of the CMS Interoperability and Patient Access final rule. That rule did also impact Medicare Advantage organizations. We are considering Medicare Advantage organizations for future rulemaking related to these policies. But this specific rule is applying to proposals for Medicaid and CHIP fee-for-service, Medicaid and CHIP managed care, and Qualified Health Plan issuers on the FFEs. So, jumping right in, and if we go to slide 2 on your deck, we will start with the Patient Access Application Programming Interface or API, and this is definitely something building off of what we finalized in the CMS Interoperability and Patient Access final rule. In that final rule, we required that impacted payers implement and maintain a FHIR-based application programming interface, specifically version 4, and that they include specific data be made available to patients

via a third-party app of their choice. So, what did we include in that original patient access API proposal? We said that impacted payers needed to make available claims and encounter data, data as defined in the U.S. core data for interoperability version one or the USCDI, that's a subset of clinical data, and formulary data if applicable. It was finalized to include data with the data service on or after January 1, 2016, that the payer maintained. So, in addition to that, what we are enhancing in this role is proposing that starting January 1, 2023, the payers impacted by this rule would also include pending and active prior authorization decision information, including relevant documentation.

So, in addition to the claims encounter USCDI and formulary data, we're proposing that, pending an active prior authorization decision, information be made available via the patient access API. To further support true interoperability, we are also proposing to require a set of HL7 FHIR implementation guides or IGs. As I am sure you remember, we suggested strongly using a certain set of HL7 FHIR implementation guides when we finalized the CMS Interoperability and Patient Access final rule, but we did not require their use. We are now proposing to require their use. So specifically, in the rule, we call out the same IGs that should be familiar to you from the original rules. So, the CARIN IG for Blue Button for claims and encounter data, the Da Vinci Payer Data Exchange, or PDex IG, or the U.S. core IG for USCDI version one data.

The Da Vinci Payer Data Exchange PDex formulary IG for formulary data. So those are all proposed to be required, and we do note, as indicated in the rule, that the Office of the National Coordinator ONC on behalf of Health and Human Services Department is formally proposing these IGs be included and incorporated by reference so they would be available to all of HHS including CMS, who potentially finalized this rule. In addition to adding some additional information to the patient access API and requiring the specific suite of IGs, we are also proposing to require something that we presented as an option in the Patient Access Interoperability and Patient Access final rule. We finalize that payers could implement a privacy policy attestation process as part of the patient access API.

We are now proposing to require that process in this rule. And, ultimately, what that process includes is an opportunity, in this case it would be a proposed requirement to have a payer request of a third-party app of the patient's choice, to attest to having certain privacy provisions in place.

Now we can require or propose to require anyway that a payer consider or that a payer reach out to a third-party app and request such an attestation; however, what we can't do is require the third-party apps to take any action, as third-party apps are outside of our jurisdiction and therefore not a requirement we can make. So, the proposal here is to require payers to request the attestation. If the app does not attest or you get no response or there is a negative response basically saying that the app does not attest to having certain privacy provisions in place, then the rule discusses that the payer would be able to share that information with the patient so that the patient could, if they so choose, reconsider sharing their data with that third-party app.

An important piece of this privacy policy attestation proposal is that, at this point, this entire patient access API process is started when a patient signs an app of their choice. So, they may be looking in their app store. They have a chronic condition such as diabetes. They find an app that uses data to help them manage their condition, and they decide that's something they would wish to use. They would then go into the app, provide their consent, authorize and authenticate their information and provide information about their payers, so that that app could then ping their payer's API. So, the patient has made a choice, and they have already consented to moving forward with this app. That said, if a patient does not respond to your information about

the privacy policy attestation, the proposal is written to basically default to sharing because the patient has already authorized this information to be shared, and they have already chosen this app. So that is the privacy policy attestation process, and it is now proposed to be required. We also note as part of this proposal that industry could choose to leverage some of the solutions that the industry is currently looking to put in place around this. So, for instance, if the third party had a list of apps that have already attested to the privacy policy attestation and specifically, we call out things like the CARIN Code of Conduct, and if there is a group of apps that are known to already meet these criteria, then that list of apps could allow a payer to forego having to also request the attestation. However, a payer would still have to have a process in place for apps that are not a part of such a collection and because something a payer would not be able to do consistent with the interoperability inpatient access final rule is single out particular apps allowed for patients.

Patients really should have a full opportunity to use apps of their choice, and the only reason consistent with the final rule that a payer could deny access to an app would be if connection between that app and the payer's API proposes a security risk for the data on the payer's system. So that's an important piece of that puzzle. So patient access API, we are enhancing with additional information through these proposals with pending and prior authorization decisions proposing the use of the specific suite of HL7 FHIR implementation guide, proposing to require the privacy policy attestation, and finally we're proposing that impacted payers report certain metrics to CMS on a quarterly basis about the use of the patient access API and specifically to metrics to get a better understanding of patient use and, ultimately, an opportunity to begin to evaluate that use with some hard data. So those are our patient access API proposals. One other piece that is included in this section of the final rule, we did also finalize a Provider Directory API in the CMS Interoperability and Patient Access final rule. In this current proposed rule, we proposed to require the HL7 Da Vinci Payer Data Exchange or PDex Plan Net implementation guide for use with the Provider Directory API. Otherwise, all requirements are finalized for that API remain consistent, and again, both of these requirements for the patient access API and Provider Directory API are proposed to be applicable starting January 1, 2023.

If you move on to slide 3 of the deck that you have, we introduce a new application programming interface, and that is the provider access API. This would also begin January 1, 2023, and this API proposal includes essentially making the same data available—claims and encounter, clinical data as defined in the USCDI version one, formulary data where applicable, and pending and active prior authorization decisions, including relevant documentation and through a FHIR-based API, leveraging the same proposed IGs as with the patient access API. The difference here is that the data would flow from the payer to the provider as opposed to the patient access API, having that data flow from the payer to the patient through a third-party app of their choice.

So, for the provider access API proposal, if the provider who would initiate the data exchange with the patient having the ability to opt into this data exchange. We do note that we seek comments. The rule proposes that a payer may put a process in place for a patient to opt in. We also considered some alternatives such as requiring the opt in, proposing to require an opt out, or defaulting to allowing a provider and payer to share these data, which is currently permitted under HIPAA for care coordination reasons, as well as a number of other reasons under HIPAA. So, these are also things we considered in this process, and we look forward to receiving your comments on the proposal to allow an opt-in process versus require opt in, opt out, or simply just default to sharing.

So that's something we'd like to call your attention to, and we look forward to your comments on that. To facilitate efficient data sharing and we also introduced the bulk data access or flat FHIR specifications under

the provider access API, and what this would do would facilitate the ability not only for payers to share data with providers one on one—say a provider has a patient coming in and they have the desire to request that one patient at that one moment in time, then that is facilitated per this proposal, but also providing an opportunity for essentially a roster of patients' data to be shared at a single time using the bulk spec that can create a lot of efficiencies and save some systems' resources as well, especially if you do have a larger number of patients that you look to exchange data on any given moment in time. And so, what the proposal states is a proposed requirement to have a payer establish, implement, and maintain a process to facilitate generating a provider's current roster to enable this payer to provider data sharing using the bulk spec through the provider access API. So, the proposals allow both an individual data sharing as well as a bulk data sharing as proposed here, and we look for your comment on both options. We do have a proposed requirement for a provider resources. This is very similar to the requirements we have under the patient access API for enrolling resources. So essentially making sure that there's information available to providers and about the availability of using the provider access API, how to use a provider access API, and any other information that would facilitate a provider requesting patient data through this API.

And we also proposed an out-of-network provider access provision, indicating that a payer would not be able to deny use or access to the provider access API based on the provider's contact status. So, in that case, this proposal would permit an out-of-network provider, who is seeing a patient, who is covered by an impacted payer to get their information to the provider access API. And there's discussion in the rule about around how to determine the relationship between the provider and the payer and where we look to provide flexibilities and where we seek comment on flexibility versus specificity and defining that roster and that care relationship generally. So that is the provider access API. Adding another API but also building on a policy finalized in the CMS Interoperability and Patient Access API, we turn to slide 4 of your deck, and that is related to the payer-to-payer data exchange. So, as you may remember, we finalized that starting January 1, 2022, payers impacted by the Interoperability and Patient Access final rule, at least the subset of payers because the payer-to-payer data exchange was actually proposed specifically as Medicare Advantage, Medicaid and CHIP managed care, and Qualified Health Plans in the individually Federally Facilitated Exchanges.

This proposed rule would actually extend the payer-to-payer data exchange policy to Medicaid and CHIP fee-for-service program. And one of the reasons we are proposing to do this beginning January 1, 2023, is because again, we are proposing that starting in 2023, this data exchange be via a FHIR-based API. So, it would be requiring additional data than what was finalized in the original data exchange. Again, the original data exchange focused on data as defined in the U.S. core data for interoperability and we are saying now, if you've got provider access API, where you're providing claims and encounter as well as USCDI data and formulary data, and it is FHIR-enabled and conformant with the suite of IGs. So how about we make that same set of data available to other payers via an API, again leveraging the same implementation guide.

So, the ability to use that work has been done and extend that data exchange from one payer to another via an API. This would cover some of the same approaches as previously finalized for the payer-to-payer data exchange. So, with the payer-to-payer API as proposed, it would be relevant to current and former enrollees up to five years post this in enrollment, and it would be for data maintained by the payer, with the data services January 1, 2016, forward, so that that piece is consistent across all the API proposals and what is currently finalized. And, as we finalized in the CMS Interoperability and Patient Access final rule, a payer would be required to send the data in the same electronic format as received. So, obviously, if you are now required to send data via the API then that would mean, under the payer-to-payer data exchange, if a patient should move

onto another payer and ask you to send the data, we would be able to send it via the API as obviously anything you had received as started on January 1, 2023. forward would also be through an API. So that should add significant efficiencies there. And, as mentioned, it's the same IGs.

One thing I should definitely call out, for both the provider access API and the payer-to-payer API, although we are proposing to include claims and encounter data, we are not proposing to include cost data for the exchange between the payer and the provider and one payer to another payer.

We do believe, as we finalize, that there's a lot of value in a patient having access to their cost data, but for the purposes of care coordination and care continuity, we did not see the same value of the cost data going from payer to provider or from payer to payer. So, therefore, cost data are not included in the proposal for sharing claims and encounter data from payer to provider or payer to payer, much like we did with the provider access API proposal and the payer-to-payer API proposals. We do also propose the ability to use the bulk data access flat FHIR specifications. And we propose one of the reasons may be most useful would be that payers facilitate sharing data at enrollment or at the end of the first calendar quarter. So, we appreciate that not every payer has a defined annual enrollment period. However, we do believe that most payers have some resurge moment throughout the year, early in the year, when a larger majority of patients make a move from one payer to another.

And so, as a result, we proposed that at enrollment or at a defined moment in time, payers set up an opt-in process for patients to be able to say at enrollment as part of the enrollment form, indicate if they would like their data shared with their new, you know from their previous payer, come to their new payer, and then at that point, the patient could share their previous payer information to facilitate that data exchange. And if you did have a number of patients from one particular payer coming in, using the bulk spec could add efficiencies there. So that is a proposal to bring in the bulk spec and a proposal to have sort of a single moment in time where there is a required data sharing, and so if, say you have an annual enrollment period and you have patients often, you would be required for the proposal to request the data from previous payers within one week at the end of that enrollment period, and if you have been requested to share data with a new payer, further proposal would be required to make that data available to the new payer within one business day via your payer-to-payer API.

We do also have a proposal under the payer-to-payer API for quarterly data sharing for concurrent payers. So, if a patient is covered by two payers, who were impacted by this proposed rule, then this would propose to have a quarterly data sharing exchange go between the payers for the benefit of the patient to ensure that both payers were fully aware and had full access to the data on their concurrent patients. So that is the payer-to-payer data exchange.

If you go to slide 5, and we have an opportunity to provide comments and how we might consider leveraging information, specifically about prior authorization decisions. So, we mentioned, we are proposing to include in the patient access API, the provider access API, and the payer-to-payer API information about pending and active prior authorization decisions. So, for a patient, this provides transparency into the process and an understanding of how that process works, what's going on, and also what services or items that they have based on the prior authorizations that have been approved, you know how many more physical therapy appointments my patient have left—that sort of information. When we're talking about the payer-to-payer

exchange of this information, what we would love to learn more from you about is whether payers should consider this information in any way.

So, if you were a new payer and you received information about pending and active prior authorizations that a patient has, we would love your input on the extent to which impacted payers should possibly consider this information and such as being limited from acquiring a patient to go through repeat evaluation or to reaffirm you know chronic condition information, before being able to access care. And, so, essentially what we're trying to understand is, is there any way for a new payer to leverage a previous payer's prior authorization decisions in order to support that continuity of care and efficiency of care for the patient, and to limit burden on the payer from going through a repeat process. So, this is something we're just seeking comment on, but we're very interested in getting your feedback on that.

On slide 6, we provide some more information about something I already mentioned, which is the Office of the National Coordinator's role and facilitating the inclusion of the implementation guide and ultimately having all those standards in one place for HHS to further support interoperability across programs and across the federal government.

Moving onto slide 7, we got into a suite of proposals around prior authorization. Prior authorization is something that stakeholders have talked to us a lot about, and it has repeatedly come up as a pain point. As not only a source of burden for all providers, payers, patients, and provider and payer staff, but also a source of burnout for providers. And so, appreciating the call from stakeholders to look at this process and see what we could do to help support removing some of these pain points, eliminating the burden and improving the process of prior authorization. We have a number of policies in this rule for your consideration. The first two proposals are application programming interfaces. So, the first is a documentation requirement look-up service. Application programming interface. And what this proposal put forth is that beginning January 1, 2023, a payer would have to implement and maintain a FHIR-based document requirement look-up service that would be in conformance with two HL7 Da Vinci implementation guides, the documentation template and resources, the DTR, and the coverage requirements discovery CRD IG.

And basically, what this API would allow was step one is proposed to require the payers to build it. And so that's what this proposal is. And then in the future what that would facilitate is the ability of a provider to discover which items and services require a prior authorization from within their workflow, from within their EHR, and what documentation and requirements are necessary in order to submit that prior authorization successfully to the payer. So, this is step one and a multistep process. At first, we're requiring payers to build it because a big part of this process is the proposal for a payer to populate that document requirement look-up service API with a list of covered items and services, not including prescription drugs or covered outpatient drugs. We mentioned that multiple times in the rule, but we will state here for clarity that the prior authorization policies in this rule do not apply to prescription drugs or covered outpatient drugs.

This items and services not including any kind of medications. So, the proposal is to require payers to list of covered items and services for which prior authorization is required and include the payers' documentation requirements for submitting a prior authorization request including a description of the required documentation. So, setting up this DRLS and populating it with the requirement is what we are proposing in this rule. And again, that would be beginning January 1, 2023.

The second prior authorization API proposal is for a prior authorization support API and again beginning January 1, 2023, we proposed that payers must implement and maintain this prior authorization support API, conformant with the HL7 Da Vinci prior authorization support implementation guide. And what this API would do is, it would facilitate a HIPAA compliance prior authorization request in response ,including any forms or medical record documentation required by the payer for items or services that the provider is seeking prior authorization. So again, we are in step one requiring proposing to require payers to build the prior authorization support API. So that it could be available to providers in the future and this would facilitate those providers and ultimately sending a request, but we immediately facilitate a payer from sending a response about prior authorization decisions.

And as part of that response, the proposal does include the proposed requirements for a payer to include approval and whether the payer approves and for how long, whether the payer denies, or whether the payer requests more information in order to complete the prior authorization request. And because we get a lot of questions and there are some wonderful, wonderful documentation on the prior authorization support IG on the HL7 website and through a number of Da Vinci accelerated program resources online, we have included on slide 8 a diagram of the data flow for the prior authorization support API.

And essentially how this works is that if it is being used within the workflow of a provider, they ultimately can discover through the DRLS API, what needs a prior authorization, what the requirements are, technically a template can come up, it could be populated with the information from within the EHR that's available. So, there's less actual documentation that would need to be filled then from scratch, but inevitably some would be.

And then that would flow from within the EHR queue, a transformation layer or an intermediary of some sort. And that intermediary could be server traditional intermediary, something like a clearinghouse, or it could be something in the house to either the payer or the provider. And that transformation layer is where the FHIR transaction is translated to the HIPAA compliance X12 transaction that then moves forward to the transformation layer or the intermediary of the payer, that is then translated from X12 to FHIR and says that the payer can then receive that request and work through that request and FHIR and then send back the other way. So that is a ridiculously high level, non-technical description of how this works, but hopefully it gets at least a good holistic idea of the concept here. There is of course like we said a lot more information provided in the rule and via the online resources. So those are the API policies that are proposing this rule.

There is one more thing that I will call out on these API proposals before I pass things off to Lorraine to dig into some of the other prior authorization support proposals and this is related to an extensions and exemptions proposal for Medicaid and CHIP fee-for-service and the proposed exception for QHP issuer. So, in the rules, there is a proposal for Medicaid and CHIP fee-for-service program. To be able to apply for either an extension or an exemption for the provider access, payer-to-payer, DRLS and has application programming interface proposals. So, if a Medicaid or CHIP fee-for-service program meets certain criteria as laid out in the rule, they could apply for an extension of up to one year after implementation to get a bit more time to implement any one or all of these application programming interfaces.

And for a Medicare or CHIP fee-for-service programs, there's an exemption proposal. For those programs, we're at least 90% of all covered items and services are provided to beneficiaries through managed care versus fee-for-service. So, the exemption is available for programs where there's very, very little fee-for-service enrollment essentially. And that exemption process would require a yearly application in order to maintain the

exemption. So, we strongly suggest that Medicaid and CHIP fee-for-service stakeholders look closely at that proposal and provide comments on the extension and exemption proposal. And then just as with the QHP issuers and the CMS Interoperability and Patient Access final rule, there is also a proposal in this proposed rule for QHP issuer to be able to apply for an exception if they cannot satisfy the requirement at any certain set of criteria again laid out in the rule. So just wanted to call out those pieces before we move away from application programming interfaces and into the additional proposals in the rule.

So, Lorraine Doo, I hand it to you.

Prior Authorization Proposals

Lorraine Doo: Okay, thanks very much. So, given that you have explained all of the technical solutions and we should just feel very confident that everything's going to be perfectly all right with prior authorization, which of course is a big misnomer because challenges for prior authorization can't really be resolved by just a single technical solution.

We know that it involves both process and policy and technical solutions. So, we're on the next slide with our other additional prior authorization proposals which we hope will help supplement some of the opportunities here, because everything has to be coordinated and implemented together in a more collaborative way. So, what we also have included in this proposed rule is some additional policies which we hope will supplement what is going to be included from a technical perspective. And the first one is the denial reason, where we are proposing impacted payers include a specific reason, and Denise have alluded to this about why they are denying a prior authorization request, so that the provider and the patient will know why something has been denied and they'll be able to act upon that denial. So, regardless of the way that the communication has gone forward, the denial reason has to be communicated and that way the provider can act upon it and if the decision will go and it enables the providers to communicate. So, this is really all about the transparency being an important element as part of the proposal and consistent with how the APIs are going to be communicating.

And we don't designate how it has to be done. And then the next part of the proposal is that we are having shorter prior authorization timeframes. These policies relate to the impacted payers not including the QHP issuers on the Federally Facilitated Exchanges, where they have to send prior authorizations decisions within 72 hours for urgent request and seven calendar days for standard request. And in the proposed rule, we have a lot of information about what historically has been the case with those inconsistency in the timeframe for when a provider can expect to have information about what the decisions will be made and this way, we'll have more continuity and when those decisions are made and when they can expect to have the information.

So that all of the payers will be responding within the same time frames and within the same communication tools. And we're hoping that this will enable both the providers and the payers to have again transparency and continuity with the information and how they'll be getting it with the APIs.

And then, thirdly, we are requiring that they'll be metrics that will be reported publicly because there's nothing better than benchmarking data to help understanding guide progress. So, we've added a proposal for payers to post their performance data in a publicly accessible website, things like the numbers of prior authorizations, percent approved, denied, approved after appeal, and averages. Again, in the name of transparency for the

prior authorization processes, which will help both providers and patients understand how the performance for the prior authorizations have gone.

The next slide we want to talk about the request for information that have been proposed for which we would like to gather some input. There are five of them that are included in the rule. The first one is a method for enabling patients and providers to control sharing of health information.

This one is based on people who want to be able to share, control the sharing of other information. Some of it which is sensitive information because people, while they do want to share and exchange information, they want to have better access and control over it, including mental and behavioral health information.

So, we're asking for future rulemaking for people to provide information about how we might control more of that, health providers and patients might be able to have better granular control over the sharing of that information. The next RFI, the electronic exchange of behavioral health information. As many of you may know behavioral health providers don't have a lot of electronic access to electronic systems and are not able to share information either with patients or other providers. So, we're hoping to get more information about how we can both remove barriers to those exchanges and what might be some incentives.

I would encourage greater electronic exchange. CMS has also been encouraged to obtain more information to the Support Act of how we might increase the exchange that information and also leverage APIs to do that. So, we're soliciting information for that request for information.

The third RFI actually pertains to the proposals we've been talking about earlier with respect to prior authorization and how we might support greater use of electronic prior authorization given that there are standards for it and we're promoting them, but how can we incentivize providers to increase their use of prior authorization, other incentives for it because it's got to be all parties participating with the prior authorization. We're supporting it from the payer perspective, but we need providers and vendors also to participate in the full scope. So, what are some other incentives that we might be able to enable to increase provider use of electronic prior authorization.

The fourth RFI is reducing use of fax machines for health care data exchange. I think fax machines are ubiquitous, but they do not support interoperability. So, we're trying to figure out how we wean ourselves off the fax machine given that it is very much a part of everyone's operational life, but we have to figure out a way to get off of it and really use more APIs and other tools for that exchange of electronic information within the workflow.

So, we're looking at some requesting information from you all about how we might be able to eliminate the fax machine, knowing how tied everyone is to that. And then finally we've gotten a lot of good input and there's a lot of excellent work going on an industry related to social determinants of health, that's our next RFI. This is exchanging social-risks data that this is very, very important in terms of being able to really manage health in the new age, particularly for public health and how we best exchange that data again some very good work going on, but how do we best collect that data and for a community-based organization's public health and other health care systems when it's so siloed and complicated to collect. So, we're looking for kind and what barriers industry faces to collecting that information, how we can most effectively exchange it and use it and use screening tools for that. Housing information, food information, and what ways we might best

exchange it. And so that is our ----- for information which listing information for future rulemaking. And as Denise said earlier, the comment period for this rule closes on January 4th. On the last slide that you have our links to the fact sheet and the rule itself. We can, obviously, will be reading precipitously and then I think I'm going to turn it over to Nicole to begin the question-and-answer period.

Question & Answer Session

Nicole Cooney: Thank you, Lorraine. We will now take your questions. I have just a few reminders before we get started. First, this event is being recorded and transcribed and we are as Lorraine and Denise had mentioned a couple times and I said at the beginning, we're looking to take your clarifying questions to help you submit your formal comments on the rule. In an effort to get to as many callers as possible, please limit yourself to just one question that will let us hear from as many people as possible. And there could be questions today that we cannot answer because CMS must protect the rulemaking process and comply with the Administrative Procedure Act. We appreciate your understanding. It's important to note that verbal comments on today's call do not take the place of submitting formal comments on the rule as outlined in the last slide of today's presentation.

And, finally, we just ask that you please be mindful of the time that you take asking your question. We have a lot of folks on the line with us. I'll be monitoring the time, and, if we spend too much time with one particular caller, I will interrupt and ask that we move on just again in the interests of hearing from as many folks as possible today and respecting that we have many on the line with us.

So, with that Blair, we're ready for our first caller.

Operator: To provide feedback, 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 to ensure clarity. Once your line is open, state your name and organization. Please note your line will remain open during the time you're providing your feedback. So, anything you say, or any background noise, will be heard in the main conference. Please hold while we compile the roster. Please hold while we compile the roster.

The first feedback that comes from the line of Jordan Johnson.

Jordan Johnson: Hey, this is Jordan Johnson, with Legion Healthcare Partners. How are you doing?

Nicole Cooney: We're doing well.

Jordan Johnson: Excellent, thank you all so much for doing this. This is much needed, actually been part of the prior authorization process on the clinical end and work with many payers. I think it's a great step in the right direction. My question is the one area, I know it's goes live 2023, but where it may fall short is the majority of our burden as with Medicare Advantage plans and then the PBM provider benefit managers. We know through CBO that they've said basically 42% beneficiary to be covered, but an MA plans could grow by that—up to 42%, but I guess that's my question is, is there a door open, I did read the rule but that the MA plans and possibly the PBNs could be included?

Denise St. Clair: So, thank you for your question, this is Denise St. Clair. We do note in the rule that we will consider Medicare Advantage organizations for future rulemaking.

Jordan Johnson: Got it, thank you so much, and I'll make sure that's in the comments, but thank you all so much, is definitely a step in the right direction. I don't want you all to think that managers is just beating us up.

So, thank you all so much.

Denise St. Clair: Thank you.

Operator: The next feedback will come from the line of Cheryl Turney.

Cheryl Turney: Hi, thank you very much. Cheryl Tourney from Anthem and also, I was one of the co-chairs of the Intersection of Clinical Administrative Data Task Force. And in that role, one of the things that kept coming up related to burden and prior authorization was the need for a patient to be able to move their prescription approval from payer to payer. And I know that the rule scoped out prescription, so I'm curious as to what the action was behind that or the decision made behind that because that was the number one thing that came out of our group related to what patients were looking for moving from payer to payer.

Denise St. Clair: Thank you for your question. This is Denise. We again as we've noted starting with the Interoperability and Patient Access final rule and moving forward, we see this as a road. This is a journey, and we are going to have several stops in this process. So, our initial payer-to-payer data exchange policy as finalized in the Interoperability and Patient Access final rule didn't require an API and was only specific to the data as defined in the U.S. Core data for Interoperability. We are now moving forward by proposing to enhance that by proposing to one user FHIR-based application programming and interface for the exchange and integrate more information into the API, including information about claims and encounter data as well as inform the USCDI data and formulary information and pending and active prior authorization decisions for items and services, excluding the prescription drugs to start.

So we will illustrate that additive process over time and sort of indicate that we are definitely interested in your feedback and encourage of course comments on all things, but interested in feedback on additional information that may be considered for future rulemaking for inclusion, but also appreciating that each piece of this puzzle requires a certain amount of work in order to FHIR enable the data and make it available and share the data, and there's obviously lots of different players in the different types of data to be made available. So, all of those things were taken into consideration and defining this stepwise process and thinking about the various steps along this road to interoperability, so hopefully that helps to answer your question.

Cheryl Turney: Thank you.

Operator: The next feedback will come from the line of Timothy Bennett.

Timothy Bennett: Hi, can you guys hear me?

Nicole Cooney: Yes, we can.

Timothy Bennett: This is Timothy Bennett from Drummond Group. Denise, when you make reference in the proposed rule of the option of using bulk FHIR specs for some of the proposed APIs, can you clarify if that bulk FHIR spec is indeed the same specifications and standards for all data exchange that HHS has already made rulemaking on through the ONC with the Cures Act for the EHR is about the same. Both data specs you are referencing here in this proposed rule?

Denise St. Clair: It is the same both data specifications. So, for the regulatory geeks on the line, that's 45 CFR 170.215. So that's where the bulk specification currently is finalized under the ONC 21st Century Cures Act Final Rule. We are proposing to leverage that now through the CMS policies, but yes, it's the same both data specification.

Timothy Bennett: Thank you very much, thanks.

Operator: Our next feedback will come from the line of Lexi Albert.

Lexi Albert: Hello, my name is Lexi. I am calling from Advanced Tandem Plastic Surgery Center. I was wondering, we are a specialty practice and so prior authorizations are very hard for us to get. We have a lot of problems with only getting three at a time or just a lot of different issues and I was wondering if there are any proposed rules that would help us from the specialist's office and getting those authorizations.

Denise St. Clair: So, hi Lexi. This is Denise. From the perspective of this proposal, we are requiring that certain impacted payers make, for instance, or implement the DRLS API, the document requirements look-up service API, the prior authorization support API, and then the additional process proposals as that Lorraine went through, so timeframes and reason for denial etcetera available, so, and we also have proposals for the payers to make the provider- access API accessible, which would include pending an active prior authorization decision. From a provider perspective, if you are serving patients who are covered under Medicaid or CHIP fee-for-service, Medicaid or CHIP managed care, or Qualified Health Plan issuers on the Federally Facilitated Exchanges say, for instance, to the provider access API if finalized that is proposed.

You would be able to request that information from a patient's payer. So, in that way that serve one intersection and then again, this role requires the impacted payers to start this process by building and populating the prior authorization API or DRLS in the prior authorization support API for future use and availability, which then could be leveraged by providers such as yourself once they are available.
So, there are some ways the provider could interact further policies as proposed in the current rule. So, I think that we can speak to today.

Lexi Albert: Ok. Alright, thank you.

Nicole Cooney: Blair, we'll take our next caller.

Operator: The next feedback comes from the line of Santosh Dave.

Santosh Dave: Good afternoon, this is Santosh Davey from New Century Health. Good presentation and good information. I have two questions that are kind of related. One is that lots of payers depend on these specialty organizations, but it's a question of specialty prior authorization for cancer, cardiac problems, and those other

things. So, from your perspective, you're talking about the connection between providers and payers. Do you see then the payers will need to build a real-time connection with the specialty organizations and the provider API is going to payer that the API will call the specialty organization API and that will respond back to payer and then payer will respond back to the practice? Can you share a little bit of your thoughts?

And the second question is a specialty product needs lots of granular level of clinical information. If you could share something on that too? Will appreciate.

Denise St. Clair: So again, I think what we can do is sort of reiterate that for instance the document requirements without service. And so, you think the DRLS will trying to be and at not only speaking acronym. But I think I did actually make an error because I'm so used to saying the DTR and CRD IGs that it is document templates and rules, that's what DTR IG stands for.

I think I had a different R in my presentation, so I just want to apologize for that. But what we are requiring in these rules as the impacted payers start this process by building the APIs and putting certain processes and policies in place that could help reduce burden associated with prior authorization and improve the process for all payers, providers, and patients.

So, your question I think is getting a little bit more at the, once available what would that connection look like or what would the data flow look like with particular specialty organizations and what we can say, the step one is say, for instance, is a documents requirement look-up service API is having the payer build it and populate it because that is quite a significant amount of work.

And so, getting that done first is step one in the process. And having the prior authorization support API available is step one in the process. So that's the requirement here. In theory and as explained in the presentations, you are looking at the flow of how to say something like the prior authorization support API works that would then right today, however, your current data flow is between a provider and a payer for a prior authorization request and the API facilitates the ability for that same exchange to happen, however for it to happen from within a provider's workflow and to definitely support the process along.

So, in terms of who the players are and that exchange I think the API itself is more facilitating the process as it works today. And then in general, the document requirements look-up service, a payer would be required to populate that with the services and requirements and descriptions requirements needed.

So that information could be eventually exposed to a provider, so that they can understand in your point some of the granular detail around what might be needed for certain specialties. So that information, the resource of the DRLS would provide the providers with information about what is needed for successful prior authorizations.

So, step one, what we're proposing here is that the payer still be these tools and then theoretically you can at least at a high level to talk about how they can support the process with the provider in the future that really are focusing on the building at this point. So, hopefully that helps.

Santosh Davey: Make sense. Thank you.

Operator: Next feedback comes from the line of Chris McFetridge

Chris McFetridge: Hi, thank you for your time. My question here is it's really too highly related questions. So, understanding the proposed expansion of payer-to-payer requirements. If a payer does not maintain specific data elements of the USCDI, is there a requirement to retrieve that data, for example, from the provider level to send based upon the API request? And similarly, if the payer receives information from another payer, that is not typically maintained with in payer system, is there a requirement to maintain that data as the FHIR resource for subsequent requests from patients, providers, payers, etcetera?

Denise St. Clair: Thanks, this is Denise. So, for the first question on if and this is obviously relevant to the provider access—the patient access, and API is currently finalized, but we do also propose through the provider access API and the payer-to-payer API proposals in this proposed rule, that the USCDI data that a payer maintains with the data services on January 1, 2016, so it will be made available through the APIs. Just like with the current patient access API, as proposed for the provider access and payer-to-payer API, it would be only those USCDI data elements that a payer can identify at the data element level and match the FHIR available via the API that would need to be shared.

So, if a payer doesn't currently maintain the data, and by maintain that we mean have access to control and the ability to share the data via the API, and then they would not need to go out and get it. So, for instance, a payer through current course of business and current processes and procedures may have some of the data elements as defined in the USCDI, but not all of them.

So those data elements which are maintained should match to FHIR and made available. Those which are not maintained are not maintained and so therefore the payer is not required, or we are not proposing to require, now the payer to go get those data and them available. So that's the first question is only what you maintain.

The second question is we have a payer-to-payer API proposal. In this rule, a payer sent data to a previous payer and stated to a new payer via the API. We are proposing, and this is consistent with the payer-to-payer data exchange is currently finalized, that the payer once they receive those data incorporate those saying into the enrollee record.

So now the data that you have received is a new payer from a previous payer becomes part of the data you maintain for that patient. So, say that same patient then request their data as a patient access API. You ingested those data through a FHIR-based API. So, they are in theory match to FHIR and available to share the data- element level and so, therefore, they are now FHIR-able data that you maintain, and you can now push back out through the patient access API.

We do propose that and you only be required to share the data that you receive via the payer-to-payer API in the electronic format you received it. So, you get it as an API data, you can share it as API data, we are not proposing, or do we currently require under the existing payer-to-payer data exchange, that a payer have to transform data they receive in any way shape or form. So, hopefully that helps address those two questions.

Chris McFetridge: Yes, that's great, thanks.

Operator: The next feedback will come from the line of Chris Craig.

Chris Craig: Thank you and thanks for the content. Chris Craig, California Department of Healthcare Services. Several parts of the rule texts refer back to detailed explanations that are provided in the patient access API writeup including the denial access. And I was hoping you could please clarify this in the context and provider access API such as reasons for denial and whether privacy attestations would be required, for example, in cases where the provider doesn't have a direct contractual relationship with the payer. So, they're not going to be controlled by contractual requirements. Thanks.

Denise St. Clair: So, I think for the—I'm definitely clear on second question but might need you to clarify that first. So, for the patients' access API privacy attestation proposal, and that is a policy that the payer would be, maybe I'm not clear on both questions, but we'll see. The patient access privacy policy attestation is proposing that a payer would be required to ask a third-party app to a tech to having certain privacy policy at provisions in place. So, it's simply the requirements you ask for that attestation and then, based on the attestation a payer receives or if nothing. No response is received from the app developer, what they can share with the patient in order for the patient sort of consider what they may want to do.

That said as we finalize the patient access, with the patient as API would need provision was a suggested or an option versus now what we are proposing. You do say that the default is to share because the patient has a right to their data, and they have already consented to having those data made available via the third-party app of their choice.

So, in that situation and the proposed requirement if the payers who request the attestation of the app and that is only for the patient access API because it's only the patient access API where data are being leveraged on behalf of the patient through a third-party app, which is outside of HIPAA.

The data exchange proposed via the provider access API and the payer-to-payer API are data exchanges that are currently ongoing, obviously not via an API in all cases, but they are currently ongoing, currently permitted under HIPAA. And, so, there is no attestation proposal for those. So, I may have covered the second piece, but if you need to give me a little bit more information on what I haven't covered, please do let me know.

Chris Craig: No, thanks Denise. I think you got it. That was what we expected, the intent is that I was just confirming. Thanks.

Denise St. Clair: Okay, great. Thank you.

Operator: As a reminder to provide feedback, 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 to assure clarity. Once your line is open, state your name and organization. Please note your line will remain open during the time you are providing your feedback. So, anything you say, or any background noise, will be heard in a conference.

The next feedback comes from the line of Timothy Bennett. Timothy, your line is open. Timothy, you may be muted on your end.

Timothy Bennett: I'm sorry, I was muted. Can you guys hear me now?

Operator: We can.

Timothy Bennett: Okay, sorry about that. This is Timothy Bennett from Drummond Group. Denise, one more question. In your presentation here on the proposed final rule regarding the prior authorization support API that payers at least that's in the scope of this proposal, that's required to implement, it doesn't seem like to me that the providers are required to use FHIR-based APIs for prior authorization as part of this proposed rule. Just that the payers are building out the support infrastructure for that. First, can you confirm that is indeed true and then, second, if so, can you comment on if CMS is considering future rulemaking that a requirement for providers for FHIR-based prior authorization. I'm assuming probably so since the rule is working to provide that support infrastructure there, but just some comments to clarify that please.

Denise St. Clair: So, to clarify the proposals in this rule are specific to payers only. So, the prior authorization support API is proposed for again the Medicaid and CHIP fee-for-service programs. The Medicaid and CHIP managed care and the Qualified Health Plan issuers on the individual Federally Facilitated Exchanges. So, in this particular proposal, we're focusing on proposing these payers to build and prepare and therefore make available of these APIs, specifically the prior authorization support and document requirements look-up service API and we do talk about the unbelievable value of providers engaging with these APIs.

And, so, obviously we see great value in that, but no providers are not required in this rule as Lorraine discussed we do have a number of RFIs. One of them is about provider adoption and provider uptake of prior authorization. So, definitely something that we are requesting comment on for future consideration is what levers, what opportunities, and what ways could we consider looking to encourage provider adoption of electronic prior authorization, specifically at these API tools.

Operator: The next feedback will come from the line of Jim Wilson.

Jim Wilson: Yes, can you hear me?

Denise St. Clair: Yes.

Jim Wilson: Okay. First of all, my name is Jim Wilson and I'm a retired pharmacist and I am also a 14-year liver transplant survivor. And one of the issues I've run into over the last 14 years is that every PBM, every Part D plan that I have been rolled into a Medicare has a same question they want to go through every year. So, are you thinking about maybe making a permanent or temporary identifier for prior authorization, things that don't change that are

For example, they just want to know when the transplant was performed, did Medicare pay or whether going to Medicare Part B or whether goes to the Part D. And it's the same question from each PBM every year.

And the second question is regarding the access to the files that would be really protected from a patient perspective and built for the patient to use as opposed to being a secondary piece. I had to make my own medical records for years because I go from doctor to doctor, they all get the same background information. So, if we had an electronic medical record that we could take from provider to provider, that would make it a lot easier for the patient. So, the question really is are you also thinking about putting in Part D plans and to make sure the patients can look up their drug costs? Thank you.

Denise St. Clair: So, yes. Thank you so much for your perspective and we really do appreciate it. Regarding Part D plans, they are not current—they are not included in this rulemaking. However, we will take your feedback back to the Part D team and in terms of patient access, we do know that is the goal of the patient access API.

And so, per the CMS Interoperability and Patient Access final rule that was published in the Federal Register on May 1st, we did finalize that Medicare Advantage organizations including MAPD plans, medications and CHIP fee-for-service, Medicaid and CHIP managed care, and qualified health beneficiaries and Federally Facilitated Exchanges starting in 2021 and officially will be enforcing it as of July 2021 given some unfortunate discretion, we exercised appreciating the public health emergency.

That basically a patient would have access to start claims in accounting data in a limited set of clinical data as defined in the USCDI through this patient access API; for that you could find a map of your choice and we're seeing those today obviously under Blue Button 2.0 for Medicare fee-for-service patient and that does include Part D information where patients could get access to their claims data and then through the patient's CHI, also their clinical data and formulary data.

So, they could view just that, have the data, and useful form that they can truly understand and take with them with the proposals in this rule that it extends patient as intermediaries with some of us as patients appreciate, but also with them allow that patient-to-provider or the payer-to-provider directly or payer-to-payer data exchange.

So, definitely the access API gets a little bit at that record piece that you were talking to and there are definitely some other pieces of this puzzle, I can support that patient access fees. So again, thank you so much for your perspective.

Jim Wilson: Thank you. I think if there was a look-up cost added, that had turn up with the very important and lifetime as well as the Part D part, that's really important for patients or not in Medicare Advantage plans. So, I don't know if you can think about that kind of data that is very critical for Medicare patients.

Denise St. Clair: Yeah, we can say that through the Blue Button, the currently available 2.0, Medicare fee-for-service and Part D claims are available to patients through the Blue Button and API. So, there's a suite of apps currently available. If you really Google Blue Button 2.0, you can find some great information on the apps available where you could as that a Medicare beneficiary access your fee-for-service and Part D claims today. So that is currently accessible.

Jim Wilson: Good. I think the other issues that delays. I know when I get lab work done, that's going to the doctor first, and then I get released to me, whereas I really should own that data, that's my data, not the doctors' control that. So, I don't know if there's anything to address the access to information that's going to be addressed with these APIs.

Denise St. Clair: A good point to along those lines to remind everyone is that much like the patient access API as finalized in the CMS Interoperability and Patient Access final rule under this proposal, we do propose the same criteria for the API data sharing, and this would be for all patient access API, provider access API, and payer-to-payer API.

That data be made available within one business day of a claim it being adjudicated or within one business day as encounter USCDI data being received. So, we do hope that helps at least somewhat with that concern around.

Jim Wilson: Thank you.

Operator: The next feedback will come from the line of Terrance Cunningham.

Terrance Cunningham: Hi, thank you. I am Terrance Cunningham with American Hospital Association. And first of all, thank you for what clearly is kind of a long years' long process of trying to alter some changes in this process. My question is concerning the comments online. With the rule having five RFIs and a significant number of times within the rule where you're asking, we solicit feedback on this portion of the rule. I was surprised and somewhat concerned that the turnaround time is so much shorter than is typically on these types of rules, and because it involves such a complex processes prior offer form, I'm wondering what the reasoning was on that and if there's any possibility that may get extended. Thank you.

Denise St. Clair: Thank you so much for your question. Unfortunately, I am able to say it's a comment deadline is January 4th. And so that's what I can share on that one. Sorry.

Terrance Cunningham: No, I understand. It's probably not—it's proving to be a rush comment period with this being such an important role. It seems foolish to try to be rushed, but I understand this is a decision, but I appreciate you taking the time to consider. Thank you.

Denise St Clair: Thank you.

Operator: We show no further feedback at this time.

Nicole Cooney: Okay, thank you very much. I wanted to let everyone know once again that an audio recording and transcript will be available in about two weeks at that same URL where you found the presentation and again that link is go.cms.gov/npc. And my name is Nicole Cooney, and I'd like to thank our presenters and also thank you for participating in today's Medicare Learning Network listening session. Have a great day everyone.

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