February 8, 2023 – Administrative Simplification Listening Session on Adoption of Standards for Health Care Attachments Transactions, Acknowledgment Transactions, and Electronic Signatures, and Operating Rules for Acknowledgment Transactions, and Modification to Referral Certification and Authorization Transaction Standards (CMS-0053-P) Transcript

Introduction

This transcript is from the February 8, 2023, Administrative Simplification Listening Session on Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard (CMS-0053-P).

Transcript

Moderator: Hello and thank you for joining CMS's national call on the Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standards proposed rule. Today's presenter is Daniel Kalwa, Deputy Director of the National Standards Group at CMS. Mr. Kalwa will begin the presentation with an introduction and background on standards for "health care attachments" – electronic transactions adopted under the Administrative Simplification subtitle of HIPAA. He'll then provide an overview of the provisions in the proposed rule. Finally, CMS will go over resources and the public comment period. CMS encourages you to submit comments on the proposed rule by March 21, 2023. The slides from today's call are posted on the Administrative Simplification website and the transcript will be posted in the coming weeks. Now I will turn it over to Daniel Kalwa. Mr. Kalwa, you may begin.

Daniel Kalwa: Great, thank you, and thank you all for joining us this afternoon. Next slide, please.

As was mentioned, it's my intention to go through a little bit of an introduction and background of this NPRM and some of the thoughts and issues surrounding it. And then I will go into a rather more in-depth review of the provisions in this proposed rule. And then I'll give you some information about how to submit comments if you like. Next slide, please.

So, as you consider this NPRM and as you consider your comments, it's worth noting three things that were included in our thought when developing this NPRM as guiderails or restrictions on what we could consider for the adoption of attachment standards.

The first is in the original HIPAA statutory language, one of the transactions identified was actually specifically identified as health care claim attachment or claims attachments. And since then, that idea has expanded somewhat, but that is what the original statutory language said. Secondly, it's worth noting that in the original HIPAA language, there was a requirement for the Secretary to adopt a standard for electronic signatures. And that standard was to be adopted to apply to the transactions adopted under Administrative Simplification. And then finally, it's also worth noting that the Affordable

Care Act revisited the concept of health care claim attachments, and Congress added an additional proviso there that whatever the Secretary adopted needed to be "consistent with the X12 Version 5010 transaction standards." So those are three things that were really forefront in our thinking as we developed this proposed rule. Next slide.

So, what we are actually proposing is first to take into account that expansion, in particular, the constant feedback we got from the industry regarding the need for attachments with regard to prior authorization. So, we're proposing a definition of attachments and health care information that is a little bit broader by removing one of those words. So instead of health care claims attachments, we're proposing merely health care attachments to be utilized under Administrative Simplification. And we also took note that utilizing these electronic documents would probably require an implementation for electronic signatures. And then while we were thinking about this and because of what we're required to propose, in order to maintain our consistency with 5010, we're also proposing to update the current referral certification and authorization transaction which is sometimes referred to just as the prior auth transaction to match what we are proposing. Next slide, please.

So, at the highest level, what we're proposing is, again, referring back to the Affordable Care Act, X12 standards that are in line with the current transaction standards to support the transaction itself, several HL7 implementation guides that will support what you can think of as the payload or the actual attachment itself. And then finally, a specific implementation guide that would adopt a standard to apply only to the attachment standards that we're proposing here. Next slide, please.

So, in order to do all of this, we first had to start at an even higher level than that and define what attachment information was in the first place. That is, when we're talking about attachments in this proposed rule, what do we actually mean? And so, what we landed on was a definition of attachment information that is specifically designed to exclude anything that already exists in the transactions.

So, the idea here is that attachment information and the attachments themselves should not be recreating or reconstructing the data that is already in a claim or already in the referral certification and authorization transaction. And so, anything that a health plan would require in order to make a coverage determination or payment determination that is not included in those two transactions would fall under this idea of attachment information. Next slide, please.

And so, we have this set. There are two X12, and I'll note there that there should be an "N" there. So, there are two X12 and 275 transaction implementation specifications that we're proposing – the claim, and one to support the prior authorization transaction, a 277, which is actually a request from a health plan to the provider which would request an attachment. And then an update to the 278 version to set an implementation specification into alignment all on the same version. Next slide, please.

As far as the actual attachments, we are proposing to essentially in total adopt all of the HL7 CCDA implementation specifications for version 2.1. So, there's several of what are generally referred to as the base implementation specification. And then there is an additional support with a document that clarifies how to implement attachments and how to implement the CCA documents. Next slide, please.

And so, when we think about attachments, and you're talking about attachment information, I already alluded to this earlier, but health plans, depending on their payment policies and, of course, depending on what contractual relationships between the health plans and the providers may ask for additional

information from a provider with regard to paying a claim or with regard to a program prior authorization. Now, this isn't always required, and it's not always necessary, but it is a process that can be intensive and time consuming to do manually.

I want to note here as we talk about these processes that we're proposing, none of the standard specifications that we are proposing or I talked about above or anything that follows, changes the general practices, the best practices or any clinical documentation requirements with regard to health care delivery. Nor does it change how health plans may choose to ask for, I'm sorry, nor does it change what information health plans may ask for. That is, it will not interfere with coverage policies or any contractual arrangements, nor should it affect the standard process that providers are already utilizing to create effective clinical documentation. The purpose of these standards is to specify a singular way in which that information can be extracted and transported to a health plan so that both sides understand exactly what the format and content will look like. Next slide, please.

So, I'm going to go through some of the use cases that we're supporting in this NPRM. The first one and perhaps the most straightforward is prior authorization. And in this case, what would normally happen is very often right now is happening is that a provider goes through a portal or makes a phone call or faxes documentation over to a health plan and then at some point later receives a response from the health plan. The purpose here, if you could go to the next slide, is to offer a more automated way to do that.

So, the X12 278 already exists under HIPAA and is already a HIPAA standard transaction in the 5010 version. What we're proposing here is to update that to 6020 and then pair it with the 275, the HL7 CCDA and HL7 digital signatures which I'll talk about later. And that would give providers an option to be able to submit the prior authorization as well as the documentation in one go from their systems directly to the health plan.

Now you'll note here that this is presumed that the provider and the health plan have already communicated elsewhere about what those documents have to look like and what need to be contained in those documents with regard to the clinical information that support it. Next would come a transaction from the health plan to the provider. And in this case, it is in the same implementation specification is a prior authorization response. So that would be in the same format, that 278 version 6020. And then once that comes back to the provider, they would have a code contained within that 278 that could then be submitted with the claim indicating that this service had undergone prior authorization and was approved. Next slide, please.

So, in this use case, it's generally referred to as solicited. And this can, this occurs when the health plan specifically asks for information from a provider regarding information contained in an 837. In this case, the service has already been provided. The providers or their clearinghouse has already billed by submitting the 837 to the health plan and either pre- or post-pay the health plan has determined that additional information is required from the provider. And so, the health plan sends a 277 to the provider systems, and once the systems are set up and if the documentation is already set up or the systems are set up, then the providers, either the EHR or their admin systems could respond directly to the health plan with a 275 version 6020 which would carry again the same CCDA documents with the digital signature if necessary. And I'll note here that in some cases this may require human intervention, and in other cases where the provider and the health plan are aware of what the documentation looks like and the provider has already packaged it, this could also be automated such that no humans on the provider's side need to actually deal with the request. Next slide, please.

In the unsolicited use case, this can actually cover a wide range of things. This is called unsolicited because there is no 277 in this transaction. That is, the provider for one reason or another is already aware of documentation requirements that would be necessary to support this service. Either all the services under this health plan require this additional documentation or perhaps the provider is in a program that might require additional documentation before these services are provided. In either case, there's no electronic request from the health plan. The provider merely submits an 837 and then at or near the same time they also submit a 275 as well as the CCDA and the HL7 digital signatures. Now, in this case, there are codes inside the transaction so that the health plan on their side will be able to link the 837 to the 275 in the event that they're separated by enough time that it's not obvious. Or perhaps they go to slightly different systems, and they have to link them up on the back end. Next slide, please.

So, I've mentioned both electronic and digital signatures repeatedly. And so, it's worth noting that when one is signing in the case of this NPRM about electronic signatures, we're talking about a broader definition of all the possible types of ways that one can sign an electronic document. So that includes things such as merely type again, signed by Dr. Smith. It could include things like images of signatures. It could also include things such as what we're proposing, a digital signature, which is a slightly more complex standard which allows for both the provider and the health plan to have a significant assurance that the document hasn't been altered. The document was in fact signed by the person that is purporting to have signed it. And that the document was signed contemporaneously with the development of the clinical information. That is, it wasn't merely created in response to the ask from the health plan or in response to the need to make a prior authorization request. Again, I said it before, and it is here again, the requirement for a digital signature does not change the signature requirements or the documentation requirements that might be applied from other legal entity. From other laws or standards or best practices. Next slide, please.

So, what we're proposing is you'll note when you read the NPRM is that there's a definition of electronic signature that is quite broad, as I imagine. And that is merely to clarify what exactly you mean by an electronic signature. And it also includes other possible approaches to electronic signatures as well as future technologies. The idea was that we didn't want to preclude other possible approaches by defining electronic signature to mean exactly what we're proposing here, which is a certain type of signature known as a visual signature. Next slide, please.

So, we are proposing an additional HL7 implementation guide which we're referring to here, and it utilizes digital certificates and digital signature technology to apply the three necessary features that we discussed in the NPRM which is identity management that is the health plan can be confident that the person signing is the person that the signature indicates it is. There is an encryption technology that allows the health plan and the provider, should it become necessary, to determine that the document hasn't been altered since it was signed. That is, it hasn't been reused. It hasn't had clinical elements of it change in order to meet the payment requirement. And then finally, it supports the idea that when the health plan receives this document, the provider can't then argue that it wasn't from them or that they didn't create the document.

I want to note, and it hasn't already been pointed out to us. We're working with the Federal Register to revise the current NPRM. It's my understanding that a little bit of our regulatory language was left out of the version that is currently available. So, as you comment on this, you'll notice that we speak about this implementation specification repeatedly throughout what's generally referred to as the preamble. But

the actual regulatory language that would adopt it is missing. When you comment, please consider that regulatory language to be there and give us to the extent that you're willing a full commentary on what you think of this approach. Despite the fact that it isn't technically specified there at the end of our NPRM. Next slide, please.

So, I've already talked about it a little bit. So, the idea here is that one would have an identity certificate which many providers already have, and many of us already have in our private lives. And the idea would be when you're doing, when a provider is otherwise signing, that is, you're generally logged in and you're indicating that you reviewed your documents and you've taken all the other necessary appropriate steps to ensure that the documents are correct, and you indicate that. The system would utilize your identity certificate to create a stamp on the sets of documents related to that service so that the, when or if you have to provide it later, either as part of a prior authorization process that another provider is doing or as part of a response to a claims payment request. That document would have been unchanged and very clearly encoded so that the time of signature and the contents are all unchanged since the document creation. Next slide, please.

And I've already mentioned this. There's a technical process that creates what is generally referred to as a hash, which is sent along with the document as part of the document. And then a computer is able to tell by looking at the hash and comparing it to the document, that the document is entirely unchanged since it was sent. That is, what the provider sent is exactly what the health plan received. Next slide, please.

So, with all of that in mind, it's now worth talking about when we're proposing to require compliance. Those who are familiar with HIPAA will know maybe off the top of your head that for new standards for transactions, the original HIPAA legislation originally calls for no more than 24 months for a compliance date from the no more than 24 months from the final rule's effective date or 36 months for small health plans. In this case, the Affordable Care Act revisited that and for attachments, it only allows us to offer no more than 24 months after the final rule's effective date. So should there be a final, when the final rule is published, the compliance date would be 24 months from that effective date. That is slightly different than what we would normally do, so that is worth noting in your comments. However, it's also worth noting that's what the Affordable Care Act says. Next slide, please.

With regard to modification, under HIPAA, a modification is a change in the standard to a new or significantly altered implementation specification for a transaction that already has an adopted standard. So, in this case, we theoretically could require a compliance date of no less than 180 days. That is, as soon as the 180 first day from the final rule's effective date, we could theoretically require compliance for this updated implementation guide. However, we didn't see any need for that, and it does offer us the leeway, so therefore, we're making the compliance date identical with the compliance date for the rest of the suite of implementation specifications for attachments. And so, in this case, it would also be 24 months after the final rule's effective date. Next slide, please.

So, I would encourage everyone to first please dive deep into the NPRM. If there's anything in my speech today that you might think conflicts with the NPRM, the NPRM is the authority. So please consider that in your comments. If you have, there are instructions in the NPRM on how to deliver your comments. If you have additional other questions that perhaps don't pertain to the NPRM or don't belong in a comment, please feel free to send us a question at the email address listed. This is, of course, also available electronically at our website. And I would also encourage you if you're interested

in future presentations and notifications on, for example, upcoming guidance, please also sign up for our email updates. Next slide, please.

And with that, I will return it over to Enzo. Thank you.

Moderator: Thanks so much, Dan. We've reached the end of the call. I want to thank you for joining us today. As a reminder, you can find the slides posted on the Events and Latest News page of CMS's Administrative Simplification website, and the transcript will be available in the coming weeks. Have a great afternoon.