



## January 25, 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 January 25, 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 Standard 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:** Thank you, Enzo. And if I could have the next slide. Enzo has already covered some of this but I wanted to speak just very quickly while we were on the agenda slide about the purpose of my discussion here is we would like to more fully explain some of the topics that I think might be a concern to those who might choose to comment and hopefully some of the background and overview will assist you in your comments that you might submit to us. And so, if I could have the next slide. There's three things that we in particular wanted to relate to you and the discussion is a little bit more fulsome in the NPRM so I encourage you all to read it carefully.

But there are three things that are worth noting, the first is that the original statute defines a health care claim attachment transaction as one of the electronic standards that were to be adopted. So that is a holdover from the original adoption of HIPAA. However, today no such adoption has occurred. I also wanted to note that there was also a requirement at the same time, for the Secretary to adopt a definition as a standard for electronic signatures under Administrative Simplification, and then I also wanted to note, and please take particular note, as we talk about the decisions that were made and the provisions that the Affordable Care Act specifically requires the Secretary to adopt health care health

claims attachments that are consistent with X12 Version 5010 transaction standards. And so that is very explicit as a bumper or a guide rail to our decision-making process. If I could have the next slide, please.

So as a summary, some of the things that we're proposing would be to first slightly expand our definition from health claims attachments to health care attachments in an effort to support both claims attachments and attachments for prior authorization. It is our purpose in expanding that to avoid having different standards and different transactions for both processes. We're also proposing a definition to be utilized with Administrative Simplification attachments, for electronic signatures as well as an implementation specification for exactly how to do that, and then we're also at the same time, and while we're working on this, proposing to update the current X12 278, Version 5010 to utilize 6020. And I'll talk more about that as well when we get to those sections. Can I go to the next slide, please?

So, as I mentioned, we're proposing to adopt a set of standards that will all work together and implementation specifications that will work together to satisfy three different use cases, which I'll talk about in a little bit, but they're generally categorized as the set of X12 standards, to meet that consistent width requirement, a set of HL7 implementation specifications and standards that describe what the attachment content would look like, and then a definition and a specification for electronic signature standards that will describe how a health plan could require the document submitted under attachments to be signed. And I want to note in particular, and I'll note it again later, we are not making any changes to requirement down signing or any changes to the best practices clinical standards or other statutory requirements around identification and signing in medical records. This is merely a methodology to do so, it doesn't change the requirements. Next slide.

And so, one of the first things we had to do when we were talking about attachments and I think, if you're familiar with the language, it doesn't really explain what an attachment is. And so in this case, we're proposing to define attachment information and that would include all types of possible attachments to be anything that is in addition to but not included in claims and the claims transaction, sometimes referred to as the A37, and then the referral certification and authorization transaction, also sometimes referred to as Prior Auth, or an X12.278.

And so, we deliberately designed this attachment information definition to be wide enough to encompass as broad a scope as possible of possible information that wouldn't be included in the two transactions but might be needed by a health plan to make a payment determination or a coverage determination. And so, it could mean anything from diagnostic imaging, video and audio, to things that might not necessarily be considered clinical documentation, such as perhaps diabetic logs or proof of delivery or a home inspection. And so if we can go to the next slide.

And so, as part of that process, there's a set of transactions that will, if you like, perform the necessary duties of addressing and performing the requested receipt of the attachment information. And here we're proposing to adopt the 6020 version of the 275, and the reason for that, rather than the 5010 version is because we identified a technical fault in the original 5010 that in certain circumstances could have caused confusion and errors in the attachment package.

So, we are proposing at this time to utilize 6020 for that and at the same time, and because we were here, we choose to propose the 277 in the same version, and the 278 in the same version, in order to maintain some similarity across the set of all these requirements. You'll note that we are not at this time proposing to update the 837 and these requirements would make no change to the current standards

requirements around claims. So, professional, institutional, or dental would be unchanged at this time. Next slide, please.

And so as far as the actual attachment itself, if you like, or the payload, or the thing inside the box that we're mailing, we are proposing a set of implementation guides that collectively we sometimes refer to as C-CDA 2.1, as well as some additional guides, for example, the Attachment Implementation Guide that was specifically designed to support this process. And these guides and these standards if you like, support and describe how one collects and bundles and labels the attachment information that would get sent with the X12 transactions, and I'll talk about that a little bit more specifically in a moment. I do want to note that we've specifically adopted this and in the attempt to ensure that what is sometimes referred to as non-structured or you might think of it as lazy documents, can also be transported through this method. So, what did I mean by that? The end vision are things like legacy PDF or Word documents that still exist in that format. As well as other older imaging and other types of documents that may not have necessarily come forward because they're archival or recordkeeping in nature, not necessarily currently clinical information. Next slide, please.

When we talk about attachments and the definition of attachments, why did we presume Congress put this transaction into HIPAA? And the idea, and it's described more clearly in the NPRM, it's that very often the case that a health plan needs additional information beyond merely a claim, or beyond merely a request for prior authorization and it's very often clinical information, but not always, and for most of these purposes, it's to make a determination about payment or coverage that would be paid later, once the provider does actually render that service. And I'll note here that this does support both a prepay model and a post-pay model for reviews. So, if we could go to the next slide.

So, I'll start with prior authorization and then we'll have an image, a little diagram and so forth through the different use cases. So, for prior authorization, under this definition, under the HIPAA definition of prior authorization, the provider is requesting the health plan's approval or if you like, guidance, before it is rendered to the patient, and they're required to send a request and then the health plan will respond with an affirmation or a denial of that request. And what that indicates to the provider is that they will receive payment should they deliver this service and then bill for it.

And so that rolls in, if that is approved, it would naturally roll into the claim process. And then the expectation is that the health plan is reviewing this additional documentation if in fact they require it, and then return the decision. And the important point here is that it would only require attachment information if the information in the 278 isn't otherwise sufficient for the plan to make a decision. And so, this does not change requirements to submit documentation to the plans, or alter any of the contractual relationships with the plans to submit information. This is the methodology, not a requirement. So, whether one has to submit a document and what those documents contain and what is considered valid to support a determination is entirely up to the plans and the standardized policy of each plan. Next slide, please.

And so, this is a simplified diagram. So what you would imagine is a provider making a request would send a 278 6020 along with the 6020 275 along with whatever documentation that's been agreed to outside of this process, usually through one of the coverage guides that a plan produces, and then if necessary, and the plan requires it, including the HL7 digital signature specification, and I'll talk more about the where's and why's of the digital signatures once we get through all of the diagrams. And then once the review process is completed, the 278 response is sent back, and the provider would then know whether they're good to go to deliver that service and can expect payment for that service. Next slide.

So in this case, it's generally referred to as solicited documents, in this case the service has already been delivered, that is the provider has already delivered the health care so we're outside of that decision cycle, and a claim has already been submitted to the health plan and at some point in this process, either before it's been paid or after it's been paid, the health plan determines that additional information is needed, and so what would happen is the 837 has come through sometime before this process is initiated, and then the health plan would send a 277 to the provider, requesting this additional information and then the attachment would be patches up into 275, again using the CCDA and sent over to the health plan.

I'll note here that it's possible for this process to be automated if the recordkeeping documents, the clinical documentation and other required business documents that are required have already been produced. That is, they're already in the EMR system and have been produced as a matter of course while delivering the service. There may need to be human intervention here, but it's not strictly necessary. Next slide, please.

And so, in the unsolicited case, in some cases, coverage requirements and this can very often be the case, for example, for Medicaid or for Medicare, providers are already aware that they need to submit additional documentation for one reason or another. So, in this case, it's referred to as unsolicited because the plan has not sent an electronic transaction requesting this documentation.

Presumably the provider is already aware that this documentation needs to be submitted along with the claim through other means. Either through coverage documents or contractual documents and the like. And so, what would happen here is in very close proximity in time, probably through the same or similar system, the claim and the 275 would be sent and now even though these are different versions, they don't directly interact except for a few fields which are compatible. So, we don't expect, but we do invite comment on the idea of mixing these two transactions. It's our understanding that this is technically feasible and should not cause any critical difficulty. Next slide.

And so, I wanted to talk more and so I've gone through what the requirements are and how it would work, I would like to talk about electronic and digital signatures and what our proposed rule is proposing to do and maybe a little bit more about what it's not.

And so, I'm sure many of you are aware that very often, a signature or an identifying review mark or something of that nature is often required in order to prove out the steps or order of operation or indicate a review of medical documentation as part of the process of clinical best practice, as part of the process of integrated reviews, and as well as the process of administrative transaction, and so one of the reasons that we're proposing now to adopt an electronic signature definition as well as a specific digital signature implementation is because we are also, we are proposing at this time to adopt a standard for an attachment transaction.

And so, what I want to reiterate is we're proposing is a methodology by which one can sign the attachments under HIPAA Administrative Simplification and a health plan can expect a provider to be able to sign using that technology. What we are not proposing is any change to any legal and compliance standards, any requirements for best practices, for in the process of clinicians or for record documentation and other bookkeeping around that might be affected by other state or federal, state, or other laws regarding document maintenance. That our proposal here is a methodology to indicate that process rather than any changes to the requirements to conduct that process. Alright, next slide, please.

And so in order to do this, we have to do two things, the first thing we're proposing to do is define what electronic signature means, and when you look in the NPRM, and please do review it, I'll probably keep saying that, we are proposing it very broadly and you'll find that it is in line with the generally generic definitions of what an electronic signature is elsewhere in rule making. And so, the idea here is that we don't want to necessarily limit the concept of electronic signature up front by limiting it to a specific technological implementation. We do have to do that later when we propose the actual implementation but the goal here is to not define the concept of electronic signature under HIPAA Administrative Simplification in such a way that we couldn't contemplate other methodologies in the future. Next slide, please.

And so what we are proposing to adopt is an implementation specification or implementation guide from HL7 that is designed to work with the CCDA and the idea here is that this specific implementation specification utilizes the concept of digital certificates and using those digital certificates, it applies an encryption and a time and date stamp, and several other process that support some of the necessary requirements around an effective signature and the requirements we're proposing, and again, I would encourage you to go and read closely why we're proposing it, applies to all signatures so even though we tend to think of the concept of pen to paper signatures as being fairly cut and dried, the same issues arise there that also arise in the concept of digital signatures.

So here we're proposing a digital signature technology as well as the accompanying encryption to ensure that the health plan when it reviews the document and when a provider goes back to look at their documents later when they've submitted it this way, can be assured that there's a correct time and date on the signature and that the document hasn't been altered. That's important to defend against even bad actors within either organization or any sort of man in the middle or duplication efforts.

Finally, the idea of non-repudiation is an important concept because of the way a digital signature works, it makes it very clear that the person who's represented as signing that document did indeed intend to sign that document at that time. And so, for those reasons, that is why we're proposing this particular approach to electronic and digital signatures. Next slide, please.

And so, I got a little ahead of myself, so, it contains, digital signatures contain a stamp or a string if you like, that indicates who signed it and when, and it also includes a third-party certificate that allows later reviewers, people that come back later to look at that document, to be confident that the person that is supposed to have signed that document, that is what it might say in text, is also the same person that signed that document.

And then at the same time, there is a larger string of characters that are created that a computer can use to verify that the document hasn't been changed since it's been signed. And so, that allows at least some steps of a medical review process at a health plan, where they need such signatures and where it's important for an order of operation for example, a lab can't happen before it was ordered. Imaging can't happen before it was ordered. In those cases, where that's necessary, this would allow an automated process for that. Next slide, please.

And I already did this one, I got ahead of myself again. And so, that is also very important when one considers not so much for prior authorization, but for claim support, attachments for claim support is not always the case that the one submitting the documentation isn't necessarily the creator of the document, so for example, a DME supplier may be getting orders and supporting documentation from a primary care physician, for example, and so they're not necessarily the ones that have created those

documents so throughout this process there's a need to ensure that the documents are true and correct and properly accounted for. Next slide.

So, as far as the proposed compliance dates, one thing I didn't mention at the beginning, because I didn't want to get overly front heavy with some of the things that the Affordable Care Act talks about. One of the things that the Affordable Care Act specifies that alters how HIPAA Administrative Simplification adoption of new standards works is that it specifically gave the Secretary a 24-month time frame in order to complete to come into compliance from the date of the final rule.

And so, what we are proposing here in this NPRM is the comply with that implied Affordable Care Act requirement of 24-months from the final rule and effective date for all covered entities. What that effectively would mean, as in previous HIPAA standards adoption, would mean health plans would have to be prepared no later than 24 months after the final rule's effective date to begin receiving the documents from providers. The important thing to also note would be conversely a health plan that is desiring to receive digital signatures as part of these attachments, that requirement would fall onto providers to no later than 24 months after this final rule to have systems that are capable of signing in that manner. And so, I believe, next slide.

Right, we also want to discuss the compliance dates for the X12 278s there, strictly speaking, under the way the HIPAA adoption rules, because there's already a 278 standard, this falls under the category of a modification. And so, the Secretary has discretion to adopt a new standard no sooner than 180 days after the effective date of the final rule.

In this case, we did not see a need to go that quickly, in particular because we're proposing this adoption to go in concert with the attachments requirements and so we are proposing at this point, not to try and go close to that 180-day date, but rather make it the same time frame as no later than 24 months after the final rule's effective date. Next slide.

So, I have gone through this somewhat quickly, but I'd like to encourage you to please refer to the NPRM and consider what I've discussed today as you consider your comments to the NPRM. You can also ask other questions about Administrative Simplification at the mailbox provided, and we also have more information that comes out through our Administrative Simplification website at the main CMS website, or you can participate in our email newsletter that will also offer updates about future presentations and actions that we might take. And with that, I believe I'm complete, Enzo. Thank you.

**Moderator:** Thanks so much, Dan. Next slide, please.

**Daniel Kalwa:** I forget that we're – I apologize, Enzo, if anyone knows anyone that wasn't here today, or you think could benefit, please let them know and it's in our newsletter, we will be, I will be conducting this session again on February 8, it will be the same information so if you're here today, you probably don't need to be here. But please, please, let everyone know that you think would benefit from this that we do have another session on February 8. Thank you. Thank you, Enzo.

**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, all.