



**The Da Vinci Project & Blue Button 2.0:
Interoperability Initiatives in Medicare FFS and Medicare Advantage**

Melanie Combs-Dyer, CPI
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Kaye Rabel: I am delighted to introduce our next speakers who will provide information about the Da Vinci Project and Blue Button 2.0. Our speakers will discuss the purpose and the goals, as well as an understanding of the role of CMS CPI in the Da Vinci Project. They will also provide an overview of Blue Button 2.0 and details about the technical build and how CMS is engaging developers.

From the Provider Compliance Group, Melanie Combs-Dyer. And from the Office of Enterprise Data and Analytics, Allison Oelschlaeger.

Melanie Combs-Dyer: Thank you very much for inviting me here today. My name is Melanie Combs-Dyer, and I am the Director of the Provider Compliance Group in the Center for Program Integrity at CMS. I oversee a number of contractors in the Medicare fee-for-service program including the Medicare administrative contractors. We call them MACs. The recovery audit contractors. We call them RACs. The prior authorization programs of the Medicare fee-for-service program. And we have quite a small number of those compared to most of you who have lots of prior authorization programs.

And I am heading up a number of initiatives in the Medicare fee-for-service program that are aimed at reducing provider burden in the Medicare program. You heard Administrator Verma talk earlier today

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about trying to put patients over paperwork and reduce provider burden. And I am here today to talk to you about the Da Vinci Project, which is one of those initiatives aimed at reducing provider burden.

There are two major goals of the Da Vinci Project. The Da Vinci Project is being headed up by HL7. They are a standards development organization, and they really have two goals in this project. The first is to improve provider to payer information exchange. So think about a provider who is trying to get information from a payer. From me. From you. From the VA. From Humana. From Aetna. From any other payer.

Think about in the context of looking for prior authorization rules or documentation rules. Today, a provider would have to ping my website, probably ping your website, and the next person's website, and the next person's website looking for those documentation requirements or prior authorization requirements. So we'd really like to see if there is a way that we could improve that process and make it so that the information would be available at the time of service and right in the provider's workflow. That's the first goal of the Da Vinci Project.

The second goal of the Da Vinci Project is going to be to help improve provider to provider information exchange. So think about a situation where perhaps a physician or a nurse practitioner is writing an order for durable medical equipment. If the patient chooses to go to the DME company that's within the same health system, it's usually relatively easy. But if they want to use the DME provider across town, oftentimes providers end up printing out the order for the durable medical equipment and giving it to the patient to take it across town or using the fax machine. So the second goal of the Da Vinci Project is to kill the fax machine.

So how are we going to do this, and who is going to do this? Well, the Da Vinci team is going to try to accomplish these goals by using FHIR

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standards. Is there anybody in the audience who has ever heard of FHIR – let me just see a quick show of hands. I don't have the fancy thing on. Okay. One or two hands is going up. This is Fast Healthcare Information Resources, or Interoperability Resources. And FHIR standards are being developed by HL7. And we think that they hold great promise to solve the two problems I just talked about, provider to payer and provider to provider.

And we are going to try to create implementation guides and sample code, and then launch pilots, very small-scale pilots, to try to test out our ideas and see if they work. And if they do, we'll share the information with ONC, the Office of the National Coordinator for Health IT, who will try to roll this out more broadly.

So who are the Da Vinci participants? So far, we have ten payers, four health IT vendors, three electronic health record vendors, and six providers. But the numbers are growing.

This is an overview of a number of use cases that the Da Vinci project is considering taking on. And I want to describe two of them today. But I want you, before I go into detail on those two, to know that there are more than just the two that I'm going to talking about today.

The two that I'm going to be talking about today are up here in the light blue boxes at the top. It's the Coverage Requirement Discovery use case. That's the one I described earlier where the provider wants to know, gee, does this patient's health insurance company have a prior authorization program for the thing I'm about to order, or the procedure I'm about to do. Or, are there special documentation requirements if I want to order a power mobility device for my patient who has Medicare.

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The second use case is very closely related to the first one. In my mind they're lumped together. And that is, if there are documentation rules, actually showing those documentation rules to the provider, and maybe even showing them a template, a sample, of the information, the data elements, that they need to include in their medical record when they're writing out their order for, for example, a power mobility device, or a particular drug, or a particular service that they want to – to order for their patient or refer their patient for.

For example, in the Medicare fee-for-service program, to be covered for home health services, the physician or nurse practitioner must have a face-to-face visit with the patient, must document that the patient is home bound, and document the skills needs this patient has. Sometimes physicians forget to write that down. So by creating a template, we can remind the physician of what needs to be documented during that face-to-face visit.

We've already created those templates. We've posted them to our website. The problem is that most physicians don't take the time in the middle of an office visit with a patient to go searching out and looking at our website. The beauty of the Da Vinci project is that we may be able to serve those templates up to the provider right in their EHR right at the time of service.

There is another use case that the Da Vinci team is going to be working on this first year, and it's one that I'm not involved in because it doesn't involve CPI, my area within CMS. It's the 30-day medication reconciliation use case. That's one that's being headed up at CMS in our CCSQ, our Center for Quality Standards. And so it's those people who will be working with the Da Vinci project on that particular use case.

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But there is another use case that I am very interested in that will start next year, and that's the one in the yellow box, medical record exchange. That's what I was describing before where two providers need to exchange information with each other about the care of a patient. It may be that they want to send the order, they want to send the – the face-to-face exam from the ordering physician to the home health agency. Or maybe the home health agency wants to send the plan of care to the physician for the physician to sign. Again, why use the fax machine if you could do it electronically.

There are a number of other possible use cases that will come in the future. They include one that is of particular interest to me, and it may be of interest to you as well. And that's the one called authorization support. That is the support for prior authorization. Up here in this first use case, coverage requirement discovery, that's just, is there a prior auth program for oxygen? Is there a prior auth requirement for power mobility devices? Is there prior auth required for home health services? Yes or no.

Down here at the bottom, it will be actually, how do I submit that prior auth request? What does the response look like coming back from the payer? So that's what that future use case is. I'm very hopeful that that is going to move up in the rank order as the Da Vinci project makes good progress as the months go by. But I'm not sure. There are lots of other use cases that are down there to be worked as well.

So why is CMS interested in the Da Vinci project? Why are we doing this? Why do we care? Well, in addition to trying to reduce provider burden, we are trying to make sure that our improper payment rate is lowered. Right now we think that the improper payment rate is too high. And by making these rules more easy for providers to find, we think that we can have an impact on bringing down our improper payment rate.

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We've also held a number of focus groups and listening sessions with providers, and we know that they believe that the documentation requirements are too hard to find. That's at least on my website. I'm not sure what your website looks like. Maybe you've got a coverage wizard. I heard Administrator Verma talking about that earlier. Perhaps, it sounded like that might be aimed at beneficiaries. Maybe you guys have coverage wizards already for providers and this is not an issue for you. But for me, for us in the Medicare fee-for-service program, we have documentation requirements all over the place. They're in lots of different manuals, on lots of different websites, and they're hard for providers to find.

And the last one is that providers are too reliant on the fax machine.

So we're going to go through a two-step process as we try to build this new system for providers to look up the documentation requirements.

The first step that we're going to undertake is building a provider documentation manual. Our first topic is going to be oxygen, and that's our topic for this spring and summer. And our goal is to actually complete four topics by the end of this year and eight topics next year.

The provider documentation manual will try to at least pull into one website all of the rules, all of the documentation requirements, a link to the template, a checklist for providers to follow for oxygen. And then the next section, and then the next section, and then the next section. So at least we are making it available all on one website.

But the second step is the one that involves the Da Vinci project. And that's the documentation requirement lookup service. We know this is going to be a long-term project, but we are starting in 2018. The Medicare fee-for-service program is at the table, and there are a number of Medicare Advantage plans who are also at the Da Vinci table.

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There are a number of private payers and a number of EHR vendors. We're hoping that in the future more Medicare Advantage plans join, and some Medicaid plans join, and more IT vendors join.

Like I said, we're working with the standards development organization called HL7, and we're using FHIR standards. And our plan is to build rules libraries that are all in a common format. So it's not that there's going to be one giant, huge repository of rules that I'm going to put my stuff in, and you guys are all going to put your stuff in. Each one of us needs to build our own rules repository and our own templates repositories. And each of us can build an API, an Application Programming Interface, on the front of our rules library that, if we do it in the right format and we use it – we build it using FHIR standards, the EHRs will be able to ping. You'll see a diagram of this in just a minute. It didn't make sense until I saw a picture. If you're a visual person, you won't get it either until you see the picture.

But we do think that this will allow the provider to discover the documentation requirements right at the time of service, right in their EHR or practice management system. And we really think it's going to help reduce our provider burden quite a bit.

So here's my picture. This is the provider in the upper left-hand corner. And the provider is interacting with their EHR. Think of it right at the time of a visit. And there's two sets of questions. This is sort of the first use case that you saw a couple of slides ago in the light blue. And this is the second use case that you saw a couple of slides ago in the light blue.

The first question set is, are there prior authorization or documentation requirements for this thing I'm about to order? I'm getting ready to order home health. Are there prior auth requirements? Well, because of FHIR, and because the patient has already registered and the EHR already

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knows what their insurance is, if they are a Medicare fee-for-service beneficiary, when the physician hits this button, it will go through this FHIR-based exchange process and out to the Medicare, the top box that's over there on the right, the top computer system, and that repository, the Medicare fee-for-service repository, will be able to return an answer back to the provider, either yes or no. Yes, there are prior authorization requirements for home health services in the state of Illinois. Or, no, there are no prior authorization requirements for power mobility devices in the state of Maryland.

Same for documentation requirements. Even if there are no prior authorization requirements, we may have documentation requirements. So both of those answers will come back to the provider right in their EHR, right at the time of service.

And it's not mandatory, it's voluntary. Providers may, if they're only doing one thing, they may already know the rules, at least for the three most common payers that their patients have. But if they're billing lots of services, and they have lots of different patients, lots of different health insurance plans, they may not always know what the rules are. So they may find that very valuable.

Next, the provider, if they got back a yes that there were documentation requirements or there are prior authorization requirements, they'll be able to click the button that says show me the documentation rules or the prior authorization rules where the templates. Again, the system will know which health insurance company the patient has, know which state the patient lives in, and will be able to go out and ping the appropriate database, the appropriate repository, and come back with here are the rules or here are the templates for that patient based on their insurance and based on where they live.

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We think that there will be other organizations who will find this rules library useful as well. Not only do I think that providers are going to want to want to use it, but I also think that some of our Medicare administrative contractors are going to want to use it.

Here you can see a number of MACs, or Medicare Administrative Contractors, who have the capabilities of building APIs of their own and coming out and pinging our database so that they can pull in the rules for home health services, or the rules for power mobility devices, or the rules for Medicare pay-for-service rules for oxygen, and use it when they're setting up their computer-assisted review of documentation systems.

Now sometimes the MACs ask us, well are you going to try to get rid of all of the nurse reviewers? And the answer is no. But we do think that sometimes computer systems may be better suited to reading those medical records and applying the rules and making the recommended decision that yes, the patient meets the coverage criteria, or no they don't. If they don't meet the coverage criteria, those are the ones that should be flagged for human review.

So here's our timeline. This spring we are going to be tasking a company called Miter with building our temporary documentation requirement repository. And later this summer through fall, we'll be hiring a company to help to visit – help build the business requirements and actually build a permanent repository. This all, of course, assumes that the pilots go well and providers actually find this helpful. I'm very hopeful. I really think that providers are going to like this a lot. And I'm very excited about the Da Vinci project.

I'm going to suggest that you guys take home a couple of questions and think about. Number one, is your organization already planning to build a documentation requirement repository? Do you know who in your

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organization sits on the Da Vinci team and is working to develop those standards? Or, are you one of those organizations who is going to let others actually build the standards, and your going to wait until that sample code comes out and then you are going to try to build your requirement repository?

If you don't have this anywhere on your radar screen at all, you're not at the table now, you've never heard of it, and you don't plan on – on doing it now, should you be thinking about it? Is this something that you should put on your radar screen for next year?

I'm hoping that you guys invite me back next year. I'd love to tell you more about the Da Vinci project and where we are in the Medicare fee-for-service program and perhaps hear from some of you about the work that – that you are doing.

This last slide shows my email address. I would really love to hear from any of you who would like to learn more about the Da Vinci project, especially if you would like to participate in the Da Vinci project.

At this time, I'll turn it over to Allison.

Allison Oelschlaeger: Thanks, Melanie. So I'm here to talk a little bit about CMS's implementation of Medicare's Blue Button 2.0. And a lot of the topics that I'm going to be talking about align nicely with what Melanie was talking about. We're also using FHIR standards. We're also building an API.

But to start with, a little bit more about Blue Button. So Blue Button is a symbol that identifies a place where a consumer can go to get their personal health records. The idea is that it is a universal symbol that ONC developed in partnership with the VA and CMS to provide information to consumers about their personal health record. Where they can go in and

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check what services they've had, potentially share their data, potentially start using apps. And that's kind of one of the things that we've been thinking about as we've developed Blue Button 2.0.

Blue Button, as I mentioned, was a project that started with ONC, CMS, and the VA. In May of 2010, CMS and the VA held an innovation event around increasing consumer access to their personal health records. And shortly after that, in August of 2010, the VA announced and released their Blue Button download functionality. And CMS set ours up in September of 2010. This download functionality gives consumers the ability to go into MyMedicareMyMedicareMyMedicare.gov and access their claims information in an electronic format, but it's either in a text format a pdf format. And so that's why earlier this year, in March, at HIMSS, our Administrator announced Blue Button 2.0, which adds a developer-friendly, standards-based API to the existing Blue Button functionality. So we're not getting rid of the existing functionality which enables beneficiaries to go in and download their data in text or pdf format, but we're just building an API, an Application Programming Interface, to add functionality to Blue Button.

Before 2018, we saw a number of pretty broad use of Blue Button, but not huge use. So we have, in total, 1.5 million CMS users. Blue Button gives access to three years' of Medicare claims history, so your hospital data, physician information, post-acute care, and then also prescription drugs in Part D. Around 20,000 to 30,000 downloads per month. And we were seeing more text downloads than pdf downloads, which at first was surprising to me. I would expect that beneficiaries would prefer a pdf format that's more, you know, easy to read, something that you can take and share with your children, your caregiver, your doctor. But what we think was happening is that beneficiaries were giving access to the text file, and we saw screen scraping going on where an application would come in and basically scrape the data and try to pull it into some other

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format where beneficiaries could actually use that information, whether as an application on their phone or program on their computer where could actually do something with the data rather than carrying around a big stack of paper. As you probably know, beneficiaries have a number of different services during the year, lots of different prescription drugs, many physician services, and so the amount of information in your claims history can get pretty big. And so we think there was some text scraping happening.

So as we started thinking about improving Blue Button, we saw the original Blue Button as really a great first step to giving beneficiaries access to their health information. But, as I mentioned, it left the patients in charge of either pulling information out of their pdf or finding somebody who could do the screen scraping for them and pull that information into some kind of format where they could use it. And what we think is that patients should have access and control over how their data is used, how it's shared. And so the vision for Blue Button 2.0 was creating a developer-friendly, standards-based application programming interface to enable beneficiaries to share their data with applications services, and research programs that they trust. Really giving beneficiaries access to their data, which is a right they have under HIPAA and the ability to share that data with their providers, with their caregivers, with whoever they want.

I'm going to jump now and talk a little bit more about our design for Blue Button 2.0. As I mentioned, it's an application programming interface, and as a non-tech person who had to learn about APIs, I think of APIs as basically two keys that are coming together. So one key is assigned to the beneficiary. And that process is integrated with Blue Button 2.0 with the MyMedicareMMedicare.gov authentication process and sign-in credentials. So beneficiaries have their key tied to their MyMedicareMMedicare.gov credentials.

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The other piece of the key for the API is the developer piece. And I'll talk in a little bit about how developers can get access to Blue Button 2.0. And so those two keys have to come together in order for data to flow. So you need the beneficiary key assigned to the bene and you need the developer key assigned to the developer before any data comes out of the API.

Melanie talked a little bit earlier about FHIR, fast healthcare interoperability resource. We're also using FHIR with Blue Button 2.0, and I'll talk in a little bit about the FHIR explanation of benefit resource, which is the resource that we're using with FHIR.

And then the back end of Blue Button 2.0 is our Chronic Condition Warehouse, so CCW, which is a integrated claims data repository that has data for the 38 million Medicare beneficiaries in the fee-for-service program.

Why do we need an API for Blue Button? So I talked a little bit earlier about some of the screen scraping that we think was happening with the original Blue Button. So that is not the most secure way for beneficiaries to share their data with resources or applications, and so an API enables beneficiaries to share their information without having to share any login information, any password information. It's kind of like when you use your Google credentials to sign in to a service, you're not giving your Google password to the service that you're using, but you're using those credentials to log into a service.

We're also allow – it also allows beneficiaries more granular management of the different services and apps that they want to connect their data to. So beneficiaries in Blue Button 2.0 will have a dashboard where they can go in and see which apps they've connected their data to, and then be

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able to turn off apps if they don't want – or services – if they don't want their data to be connected to that service any more.

And then the API puts the data in a structured format, the FHIR format, so it makes the processing much easier for the application or service that's using the data. It's much – it's standardized, so, you know, if you pull the data today, and then in three months you pull the data again to what services the beneficiary has had over the course of the three-month period, the data format will stay the same, the same variables will be there, so it helps to enable app developers and services to build tools and not spend a lot of their time just managing changes to the structure of the data.

We wanted to use industry standards when we were developing Blue Button 2.0, and that's why we decided to use the FHIR standards. The HL7 workgroup that has created the FHIR standards has gained significant traction with their standards. The Da Vinci project is using it. There are other workgroups across the healthcare industry that are using it. We see it used frequently in EHRs, and so we wanted to use a standard where it was something that was used across the healthcare industry.

We chose the explanation of benefits piece of FHIR, which isn't as commonly used as some of the other pieces of the FHIR standards. But because it's the most relevant to claims information. So it has both the claim, so the diagnosis, and procedure information that a physician would put in, and then it has the claim response. So that payment information. And you can see on the right side of the screen there all of the various pieces of the FHIR explanation of benefit is what the CMS team did in mapping the claims information to the FHIR EOB as we spent a lot of time thinking about, okay, what are our claims elements, and how do we take those and connect them to the correct FHIR elements. We've posted all

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of that information publicly on our GitHub repository, which is a place where developers can go and find information, because we want to be transparent with how we're mapping the data between the – the standard kind of claims fields that a researcher or a provider who uses our data is familiar with and the EOB.

And we also want feedback because we're not 100% sure that we've mapped all the fields correctly. So as we've launched Blue Button 2.0, one of the things that we're trying to do is engage with the developer community to make sure that with – that we've correctly mapped these fields. And so it will be a work in progress as we move forward with Blue Button.

A big piece of giving beneficiaries access to their health records is making sure that you have the necessary – necessary authentication and authorization access controls in place. So I broke this down into two pieces. The first is authentication, so making sure that the beneficiary who is getting the information, their actually getting their own health records and not some other individual's health records, which is obviously incredibly important when you're sharing personal health information.

We were lucky with Blue Button 2.0 that we have been able to leverage the authentication process that MyMedicareMMedicare.gov has set up. So we're able to use the credentialing that they've done, the identity-proofing process that they have in place already. And so then we can just take those credentials and apply them within the Blue Button 2.0 project.

The second piece is making sure that beneficiaries are able to control which apps patients or services are accessing their data. So this permission process, as I mentioned before, is familiar to a lot of folks who have smartphone applications or use social media to connect into different services. And with the goal that beneficiaries are never sharing

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their password information, their User ID information, and that they can always control who has access to their data and have the ability to turn that – that access off at any point where they don't to allow access any more.

We also thought a lot about how we were engaging with developers with Blue Button 2.0. So there's obviously the technical build piece. And there's the beneficiary piece. But we also want to make sure that there are applications and services that are able to connect to Blue Button 2.0 to offer ways for beneficiaries to use their health information or share their health information.

So back in January we launched our developer sandbox. This is a pool of 30,000 synthetic beneficiary records and the associated claims. And basically what synthetic data is, is it's fake data that looks like real data. So we took real Medicare claims information and beneficiary information, and basically scrambled it all up. It doesn't have any name or direct identifying information, but then any information that could potentially be identifying, like a birthdate associated with a diagnosis code, those are scrambled. So it's not associated – the birthday may be associated with Melanie whereas the – one of the diagnosis codes would be mine, and another diagnosis code would be associated with some other beneficiary. But it gives the real experience of working with claims for these developers as they work to build applications and services.

Developers are able to quickly get access to the sandbox. We wanted them – we do collect a little bit of information about them just to make sure we're able to continue to engage with them and – and get their feedback about using the sandbox and using the API, but it's open to anyone, and we currently have over, I think, 250 – getting close to 300 now – entities that are engaging in the sandbox. And I think this morning my team told me that we have 500 developer – individual developers who

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are working in our sandbox playing with this data and thinking about how – what types of applications and services they can offer to Medicare beneficiaries.

We also thought a lot about how we would authorize developers to get production access. So any developer who wants to can get access to the sandbox to play in the fake synthetic data, but when developers were going to get production access, access to real Medicare beneficiary data provided the beneficiary had authorized that access, we wanted to have a couple of steps in that process.

So CMS reviews all applications before production access is granted. And, as I mentioned before with the API, there's always two pieces of that key, right? So even if a developer has production access, the individual beneficiary must authorize access to that application. So a developer would never get access to a beneficiary's information unless the beneficiary themselves had offered to provide it – had given that application or service access to their information.

We have a couple steps that developers go through. They have to provide us with information about their terms of service, their privacy statement, in plain language that explains to beneficiaries how their data is being used. We also have them do a demo with our team to show us what kind of application that they've built so that we can evaluate if it's relevant to the Medicare population.

One of the – the focuses of our Administrator is putting the patient at the center of the healthcare system, and the idea of Blue Button 2.0 is giving them the data – their data so that they can do – so that they can be at the center of the healthcare system, right? So with Blue Button 2.0, we see a number of different uses, whether it's applications on your phone to allow you to track prescription drugs, or upcoming doctor's visits that need to

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happen, upcoming preventative tests and that sort of thing. Whether it's just having a personal health record so that you can keep track of all the services that you've had. We see a huge research piece of Blue Button 2.0 and have been working with the Assistant Secretary for Planning and Evaluation in the patient-centered outcomes research efforts across the department to think about how, with Blue Button 2.0, beneficiaries can donate their data to research or if they're participating in a clinical trial, share their data so that adverse events, for example, can be tracked.

And then also for care coordination purposes, potentially, if a beneficiary wants to share their data with a provider, a new provider or a provider that they don't see very frequently, so that that provider has information about labs, or images – imaging services that the beneficiary has received over the past few years that the beneficiary may not remember or have great information on, but it is all there in their claims history.

As I mentioned, we announced a production launch of Blue Button in – at HIMSSMSSHIMSS on March 6th with Administrator Seema Verma's speech. And we have over 250 developers that are playing in our sandbox. And we have granted production access to our first cohort of apps, so we have a couple of applications that are starting to work with beneficiaries to get access to their data.

I talked about this a little bit, but we do see a number of use cases for Blue Button 2.0. But we're also excited to see what types of application services, research programs, care coordination tools decide to connect to Blue Button 2.0. I think that one of the cool things about this for me has been seeing the types of entities that come in and want – are interested in getting access to the Blue Button data. There's just so many different ways that beneficiary data can be used, and giving beneficiaries access to their information and the ability to share it with whoever they want has so many different purposes that we can't even imagine.

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If you're interested in learning more about Blue Button and kind of what we've done to build Blue Button 2.0 within CMS for the fee-for-service population, you can visit our website, BlueButton.CMS.gov. We have a lot of information here kind of going into more detail about documentation for developers and connections to our GitHub repository which is where we have more detailed information about how we built the API. We really focused on open source and making sure that we're very transparent with how we built Blue Button 2.0. We also have just started a blog to start to communicate with developers around whether there are things we're fixing, or best practices for using the API, that sort of thing. So we'll be posting more information to BlueButton.CMS.gov as it becomes available.

With that, I will hand it back over to our moderators.

Stacey Plizga: Okay, we do have a couple minutes for questions, so if our in-house audience has any questions that they would like to ask, please step to the microphone in the center of the aisle.

Okay. No questions, huh? All right, then. With that I would like to thank Melanie and Allison for the great information on the Da Vinci project and Blue Button 2.0.

Well, it's that time again to evaluate this session, so please take out your phones and text A as your response if you would like to evaluate this session. If we have any of our session speakers out there, if you could move to the front of the room, we would certainly appreciate that.