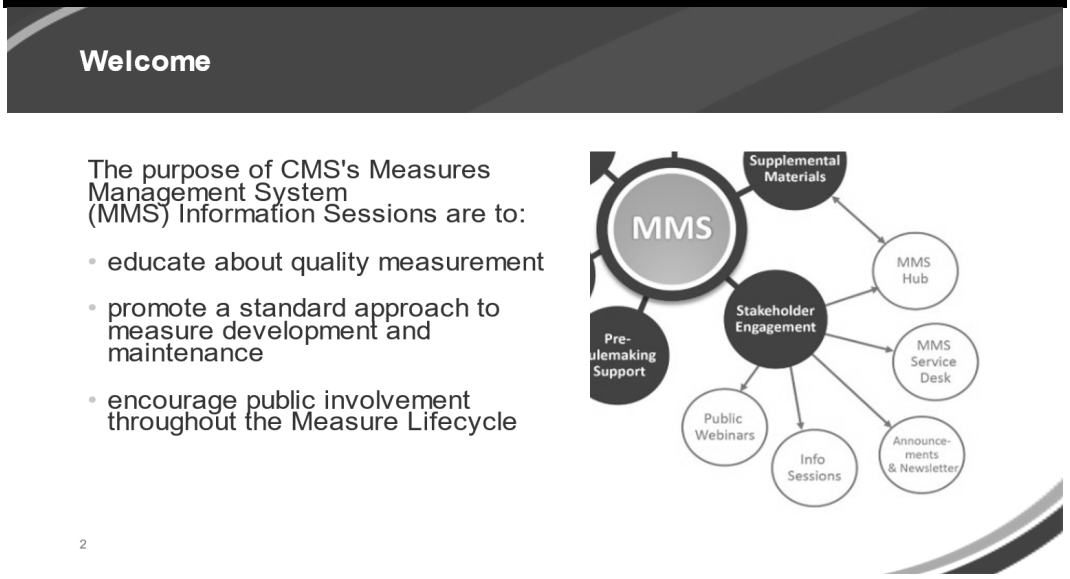
[SLIDE 1]

VON HOLST: Thank you for joining us. It looks like our attendees are starting to slow down here with folks joining, so I'll give a quick introduction and we'll jump in.

[SLIDE 2]

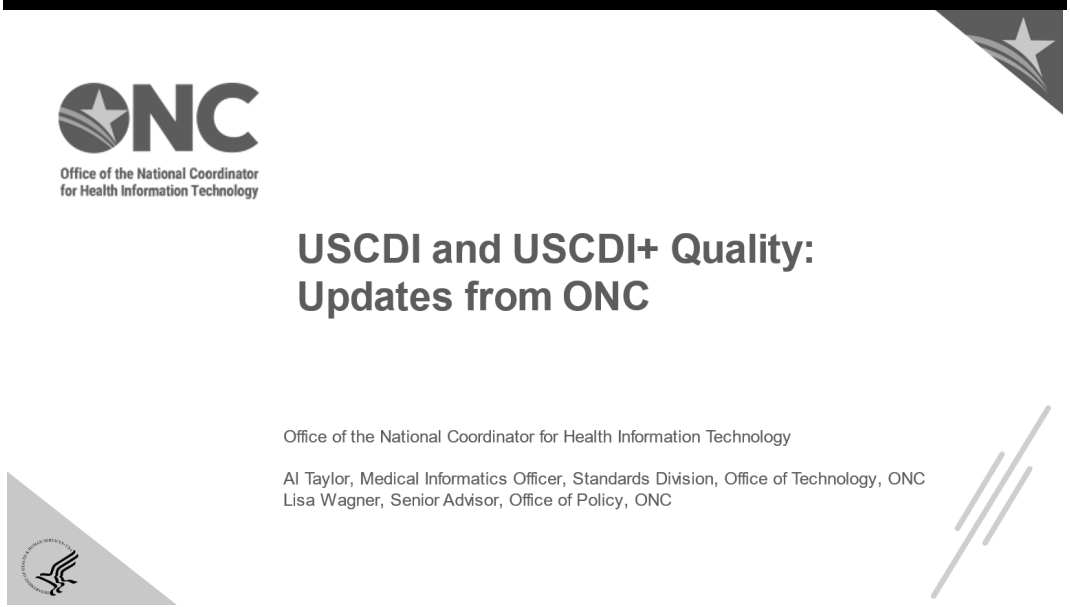


VON HOLST: Good afternoon and welcome to our November Information Session. Today we're going to be talking about US Core Data for Interoperability for USCDI and USCDI+ Quality. So we're going to be talking about what they are and what's ahead. My name is Haley von Holst and I am the Information Session Lead for the CMS Measures Management System (MMS) contract supported by Battelle. So we're joined here today by two presenters — I'm very excited to have them — from the Office of the National Coordinator for Health Information Technology (ONC), Al Taylor and Lisa Wagner. So again, we're so excited to have them here to dig into this topic. They are our experts.

If you would like to download today's slides, they're available on the MMS Hub. We will also post a recording of today's session on the MMS Hub in a few weeks and so you should have access to that as well.

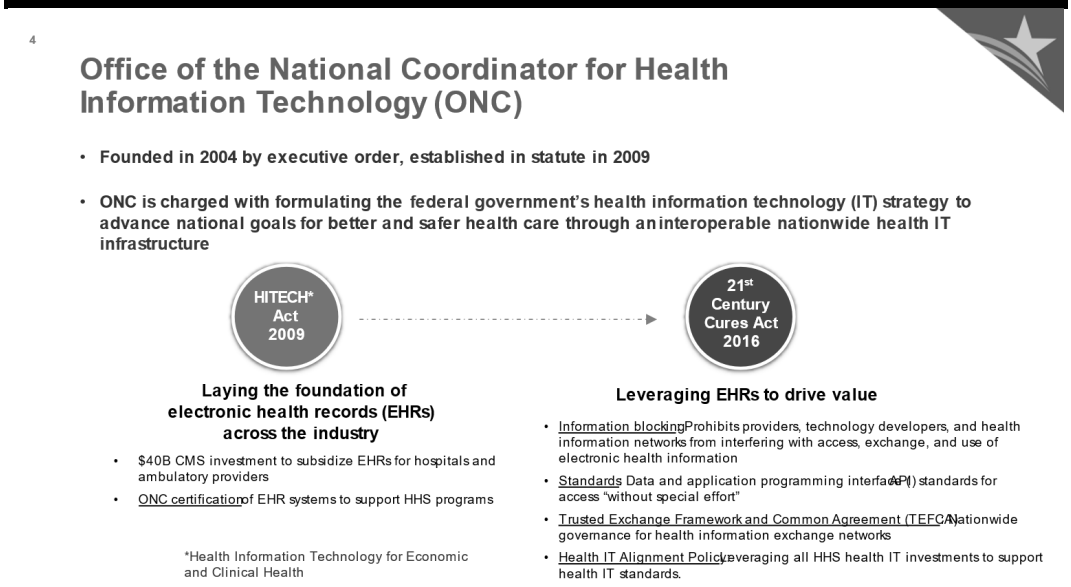
Okay, so as part of the Measures Management System's outreach task CMS produces these Information Sessions throughout the year to educate about quality measurement topics to engage those interested in measure development and maintenance. So in short, we host these sessions for you all. We highly encourage you to submit questions throughout today's presentation using the Q&A feature near the bottom of your screen, and we'll try to address as many of these questions as we can at the end of the presentation. So thank you again everyone for being here, and I'm going to turn it over to Al to get us started.

[SLIDE 3]



TAYLOR: Thank you, Haley. Again, my name is Al Taylor and I'm a medical informatics officer in the Office of Technology at ONC. I am originally, by training I am an OB/GYN. I served in the Army for 24 years and came to ONC about eight or nine years ago, and I've been working in standards. In particular I've been the technical lead for USCDI coming up on five years now as we get into our fifth year of USCDI.

[SLIDE 4]

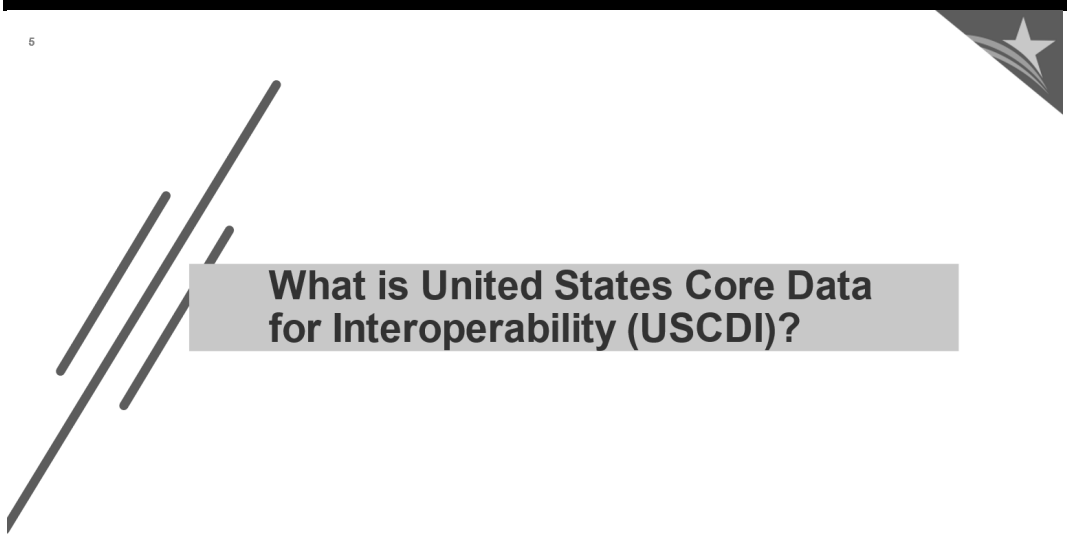


TAYLOR: The ONC, for those who don't know, was originally founded in 2004 by executive order. It was a very small office in the immediate office of HHS but the fund really got started in 2009 when our authorities were outlined in the HITECH, Health IT and economic and clinical health law, and that defined the meaningful use program. It identified certain things that set ONC as the authority in establishing those criteria for what meaningful electronic health record (EHR) information is supposed to accomplish.

We have done that and we've executed our certification program now for the last ten plus, almost 12 years now certifying or authorizing the certification of Health IT for a variety of different purposes, not the least of which was CMS in the use of electronic health information in CMS reporting programs and CMS billing programs. Our overall goal is to achieve interoperability of Health IT.

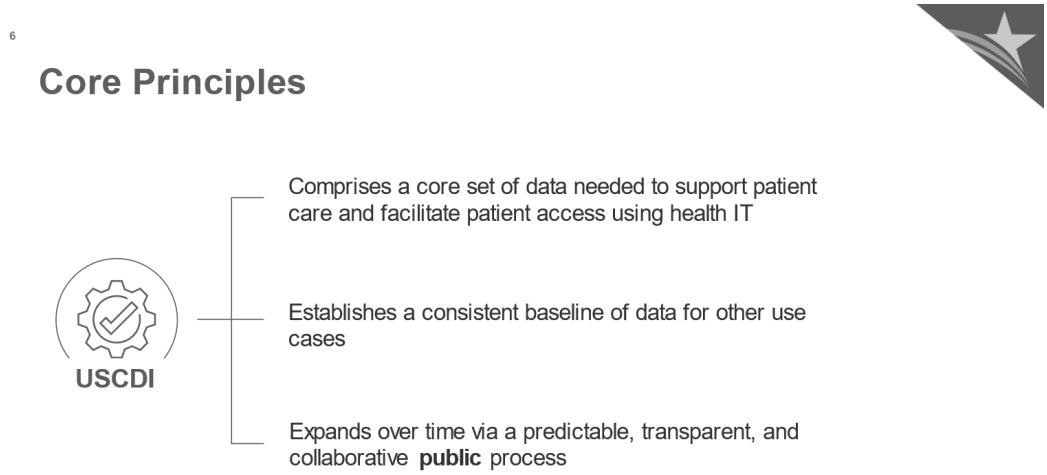
We were granted further authority in the 21st Century Cures Act, written in 2016. A lot of our authorities were rewritten when our Cures Act addition final rule came out in 2020. It includes covering things like information blocking, identification of additional standards, the concept of the Trusted Exchange Framework and Common Agreement or TEFCA. And also some authority to work to align Health IT policies and standards across all of HHS.

[SLIDE 5]



TAYLOR: The USCDI, the United States Core Data for Interoperability. What is it?

[SLIDE 6]



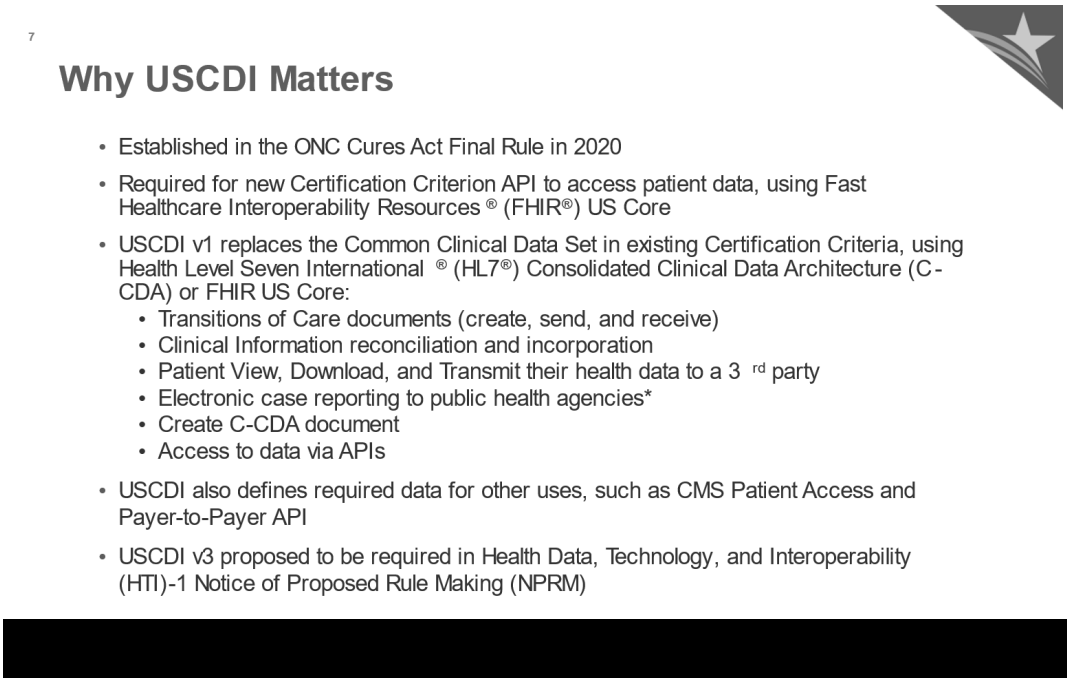
TAYLOR: It's several things. One is it's the core set of data needed for patient care and it's the core set needed to inform patient access to their health data. In addition to identifying this set of data required and needed and desired for a variety of different purposes, it's also come to serve as a *baseline* for other uses. So when other HHS agencies or federal agencies have a particular need for health data for whatever that purpose is, be it CMS reporting, Social Security/disability ratings, or anything else that might be used — the USCDI stands as a baseline.

Some reporting programs and some federal agencies may require additional data above and beyond what USCDI is, but we can always refer to USCDI as the base. If we need extra stuff, those programs can identify those, rather than going into every little detail about every part of what's part of USCDI. So it's that baseline,

even though it's a moving baseline, it is the baseline that can be used by others for reference.

When we established USCDI we created a predictable, transparent, and collaborative process. We try to hold true to each one of those components of this process. It is public. The expansion is based directly on public input, and that public input can come from agencies, a man on the street, a person on the street, or other organizations within healthcare and elsewhere.

[SLIDE 7]



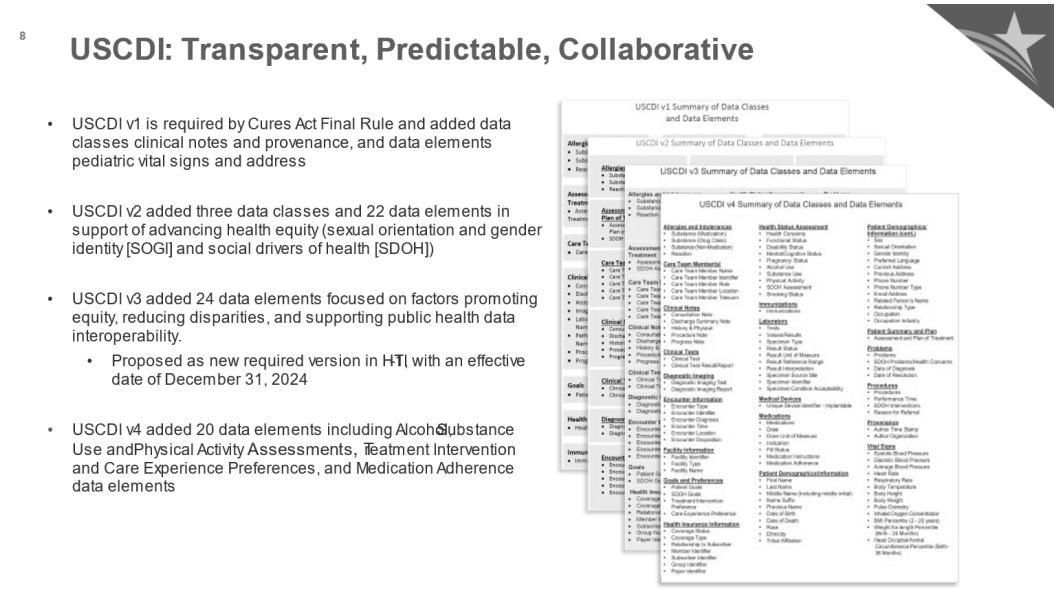
TAYLOR: This outlines some of the same things. The key point to take away is that USCDI identifies the datasets. Other parts of the ONC certification program define how that dataset is used. Interoperability is a key part of USCDI. It's the actual "I" in the USCDI, and the "interoperability" means that that data has to be able to be exchanged — accessible, readable, understandable and exchangeable. That exchange happens through a couple of different mechanisms that are

defined by our certification program. One of them is the Consolidated Clinical Data Architecture (C-CDA) which has a number of different templates or document types that can be used to exchange data in different formats. The contents of those C-CDA documents include USCDI data. Similarly, a newer mechanism of transfer of exchange of information is through FHIR, Fast Healthcare Information Resources. This is a machine-readable exchange format and the content of the information that's exchanged using the FHIR or in this case the US Core build of FHIR, the information that is contained within those exchanges and so in FHIR resources — are defined by USCDI. There are other things in FHIR resources that USCDI sits at the core of that information that is exchanged using those mechanisms.

USCDI, this was as the definition of USCDI's Version 1. As most of you know, ONC published their new certification and other Health IT rules called *HTI-1*. It is currently in notice of the proposed rulemaking process, or it's in rulemaking. It's not finalized yet. There are some specific stipulations that change how USCDI is used and required and we hope to publish that soon.

And then should those changes be implemented, those will override past requirements under USCDI Version 1, but USCDI Version 3, which we'll talk about in a minute, is the new standard. It would be the new standard when this rule is published, that this rule will be published as is.

[SLIDE 8]



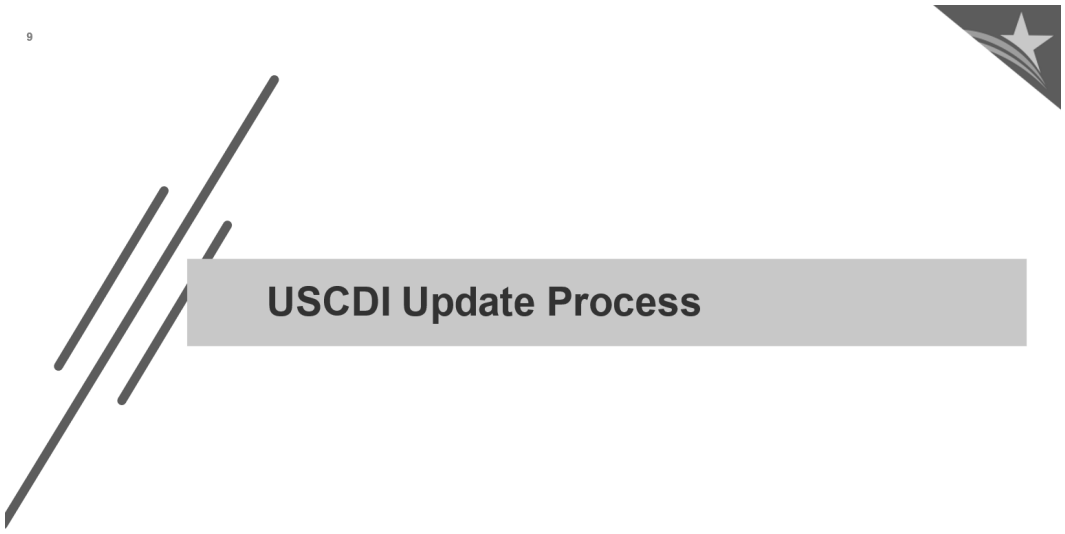
TAYLOR: This shows the progression using this transparent, predictable, and collaborative process. USCDI Version 1 started as an expansion of the common clinical dataset which previously was used to exchange information using ONC certification criteria. USCDI Version 2 added a couple of different elements. It added some additional data elements, and in particular they expanded the availability of SQH data and several key demographic components including sexual orientation and gender identity. We also made other expansions in other areas as well, adding several data classes that did not have a footprint in the common clinical dataset, USCDI Version 1.

USCDI Version 3 added additional data elements and classes focused on the administration parties around promoting equity, reducing disparities, and supporting public health and data interoperability. As I mentioned, with a few

modifications to Version 3, it is proposed to be the new baseline standard. That effective date is not going to be the reporting date. That was tentative as of its initial publication of this proposed rule. We don't have an exact final date, but it should be some time down the road, perhaps a year or more after this date.

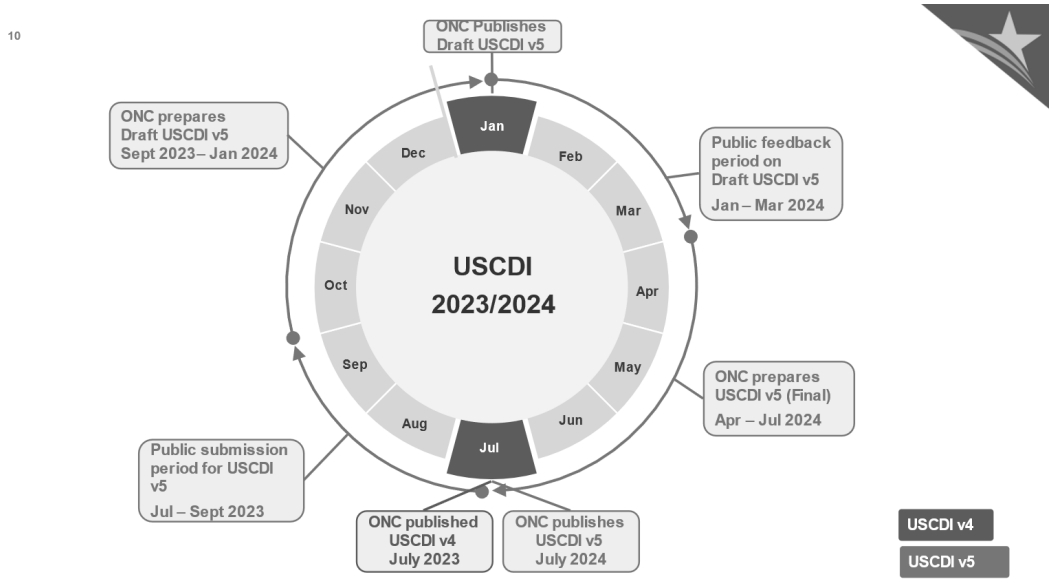
Finally, the USCDI Version 4 which we published in July as additional data elements in a newly expanded health data assessment data class, including some additional information that is useful during the medication reconciliation process and the development of advanced care planning documents.

[SLIDE 9]



TAYLOR: As far as the USCDI process goes, I'm going to dive a little bit into this, because many of you on the call have participated reactively in this process and we're aware of that. We want to just highlight what we are doing and what we intend to continue to do.

[SLIDE 10]

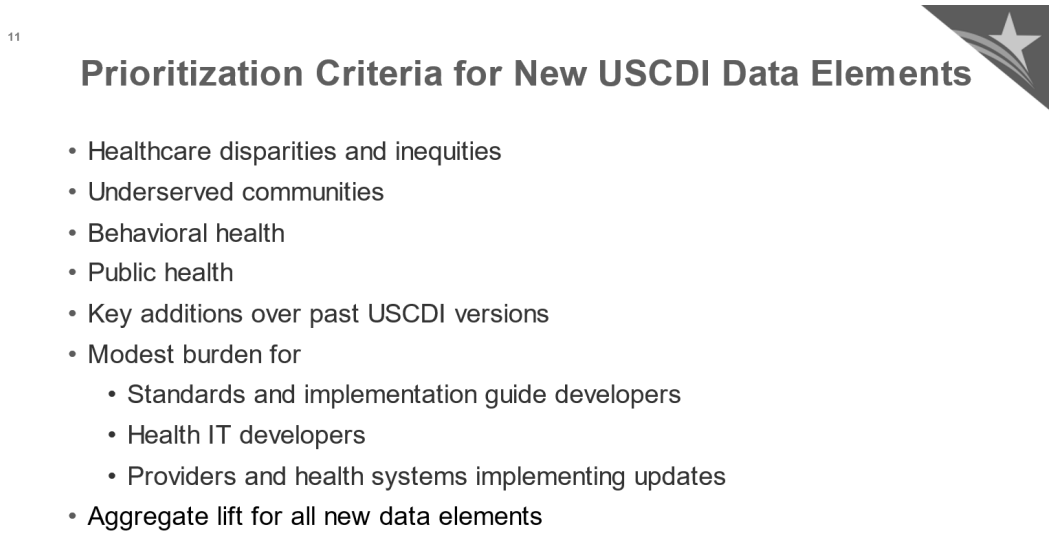


TAYLOR: USCDI is in a cycle, and at any given time we might be working on different aspects of different versions of USCDI. USCDI Version 3 was just made available for updating this summer, as we were working on Version 4, which we had a submission and comment process that ended. We finished the submission and comment process on USCDI Version 4 and published the final in July, but at the same time we were collecting information on what ought to go into USCDI Version 5. That includes submission through our new data element request system and comments on data elements that were submitted for addition in the past, but not added to a previous version of USCDI.

So we reviewed those comments and we reviewed those submissions, and we are now in the upper left corner of this cycle or this quadrant of the circle working on what is going to go into draft v5. Once we publish draft v5 in

January, we are going to go through an approximately three-month public comment and review cycle, including getting input from our HITECH committee or advisory committee. We will digest all of those comments and feedback and then develop what ends up going into the final. It could be more data elements. It could be different data elements. It could be less data elements, but this will all be based on the input that we got during the January to April timeframe. And then we hope to publish USCDI Version 5 in or around July of next year.

[SLIDE 11]



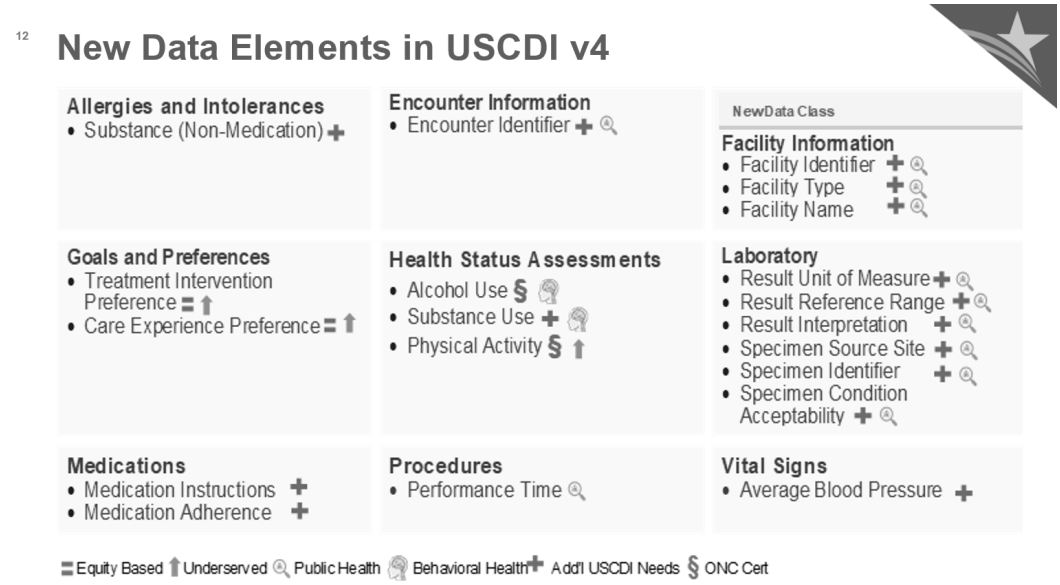
TAYLOR: We get a lot of submissions and comments on previously submitted data elements about what should go into the next version or another version of USCDI. We have to evaluate the maturity and readiness of every single data element that is submitted. Some are ready to go. They could potentially be adopted if they were in policy. Other ones need additional standards development work. They need additional testing, and those are ones that are not immediately considered for addition to USCDI, but with additional work —

piloting, testing, implementation, Implementation Guide (IG) development — they could be considered for future versions of USCDI.

We went through that whole filter of leveling these out for maturity and readiness, but we still have many more data elements than we can add. We are limited in the ability to add a certain number of data elements in USCDI, and we have this concept called "aggregate list" that's at the end of this list. It means that we could have a lot of great ideas, a lot of very mature data elements, but we are not in a position to put the burden on standards developers, Health IT developers, and actually providers in implementing systems that have to digest that and then put that into practice.

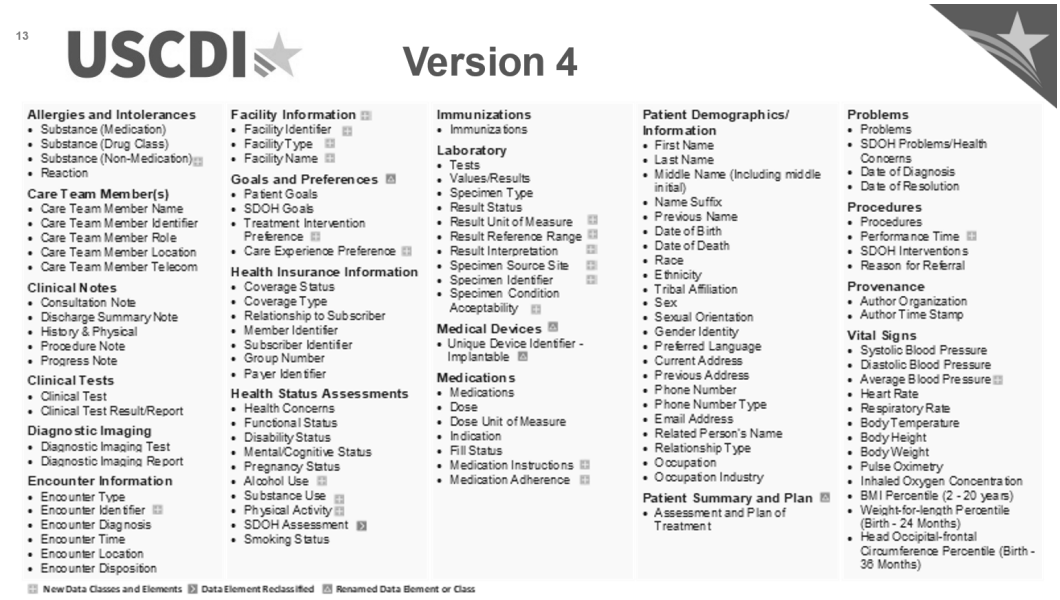
So in addition to considering new data that addresses healthcare disparities, underserved communities, and behavioral health and public health, we have to also consider some of these technical criteria listed in the second half of this list as to how we come up with that final list of additions. In the past we have added on the order of 20 new data elements in each of the last four update versions of USCDI and that pattern will likely continue. It's somewhere in the ballpark of that number. It's not an exact number, but we have to be considerate of those who are going to take that and put it into practice.

[SLIDE 12]



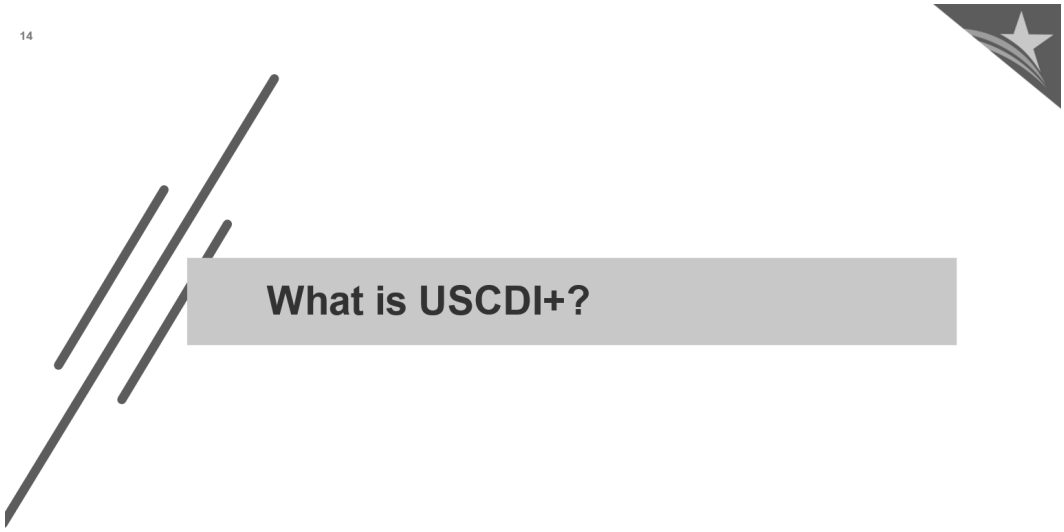
TAYLOR: This is just a quick overview of the new data elements that we added on the USCDI. I've mentioned the ones that we did add. We had a significant expansion in laboratory data elements which helps the public health reporting systems gain access to and help mobilize those data, new data elements in facilities, medication, data class, and then several new health status assessments. So I'm not going to go through each one of these, but these are the new ones that were added. The little symbols relate to the prioritization criteria that we mentioned on the previous slide.

[SLIDE 13]



TAYLOR: And this is just a summary of all of the data elements that comprise USCDI Version 4.

[SLIDE 14]

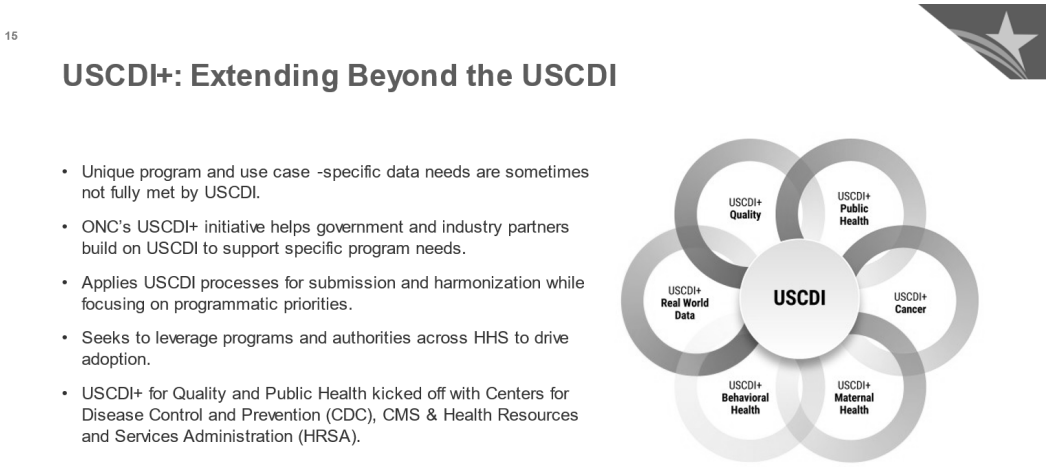


TAYLOR: I'm going to turn it over to Lisa Wagner who's going to talk a little bit about kind of what happens. We have USCDI at the baseline and then where do we go from here.

WAGNER: Thank you, Al. My name is Lisa Wagner. I'm a senior policy advisor in ONC. I've been working on USCDI+ for the past year or so. Though, as you all heard from Al just recently, we learned over the past several years working in USCDI that there was a clear call and need for more program or domain-specific data element lists. So then ONC realizing this hearing from partners and realizing that USCDI is only expanding incrementally over time with really core data elements that we did find this need for more domain-specific data elements that could be an extension to what is the current USCDI. We've been working over the past couple of years to develop a collaborative process for partners to

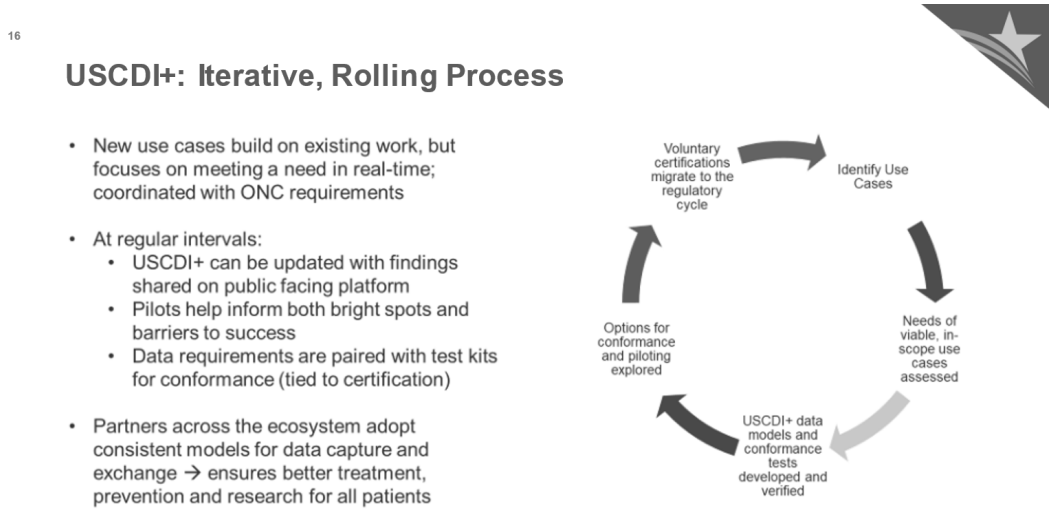
sort of coalesce around specific programs, requirements and data element requirements for programs. ONC officially launched USCDI+ in the fall of 2021, though that's when it was first announced. We've really been spending the past couple of years trying to figure everything out.

[SLIDE 15]



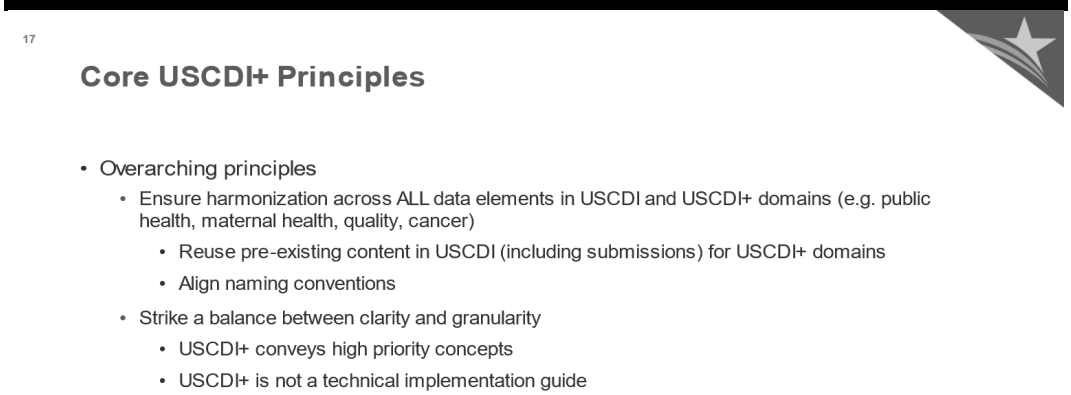
WAGNER: So just as USCDI expands incrementally over time via a transparent, established and collaborative process, and weighing both benefits and impacts on industry, USCDI+ is intended to *mirror* a similar process, an established data element list to harmonize and align data needs for partners. When we set out on USCDI+ our initial domains were quality and public health. Over time we've continued to expand our focus to also include cancer, maternal health, and behavioral health program needs. Really our initial start is around just the sheer need for alignment across these different program areas and we'll continue to work on this alignment over time.

[SLIDE 16]



WAGNER: As I mentioned, USCDI+ is meant to be an iterative process where we're making changes and updates on a rolling basis similar to USCDI. So this work will allow partners within and outside government who are working in the same program areas to be able to reference the same data standards or data elements as well.

[SLIDE 17]

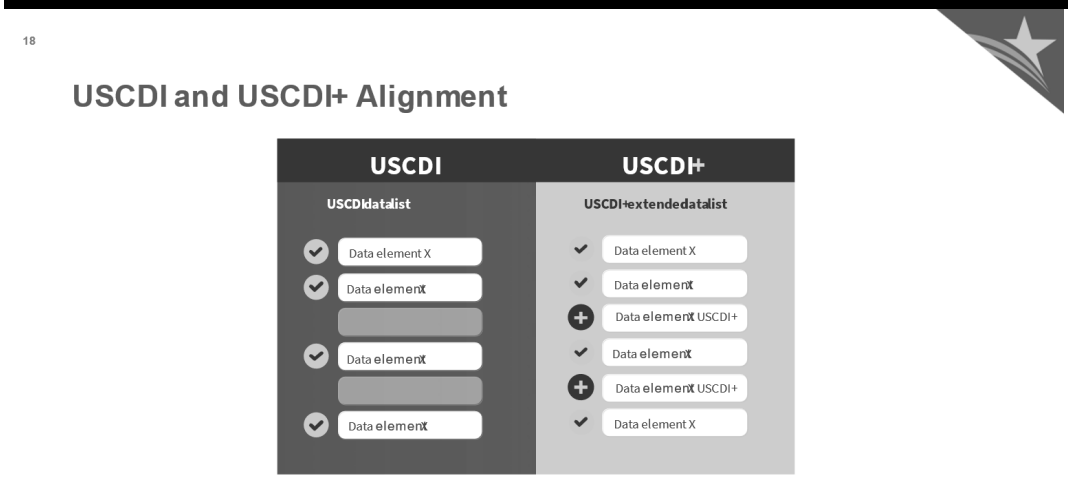


WAGNER: So the overarching principles of USCDI+ are around harmonization, and so the idea being that we're starting with USCDI as our base and first doing an analysis there to see of these particular program areas we're focused on whether that's quality, cancer, public health — what really overlaps with the existing USCDI data element list? We're also trying to across domains align those same data elements, working to think through as we're adding in additional data elements for quality. Does that also apply for something like cancer or public health as well? This is to really try to harmonize as we're going along, all along trying to align these different naming conventions. Really there's this balance between granularity and clarity in the sense that USCDI and USCDI+ aren't necessarily the details down to a particular Implementation Guide (IG).

They are intended to be a higher priority concept, and our hope is that over time we can still reference specific buyer standards as a part of the particular data

elements we've identified, but also to build a community around gaps in specific data standards where we can say within a quality program or within cancer that if there are data standards that are missing, that we're identifying that across different program areas and working together in this collaborative process.

[SLIDE 18]

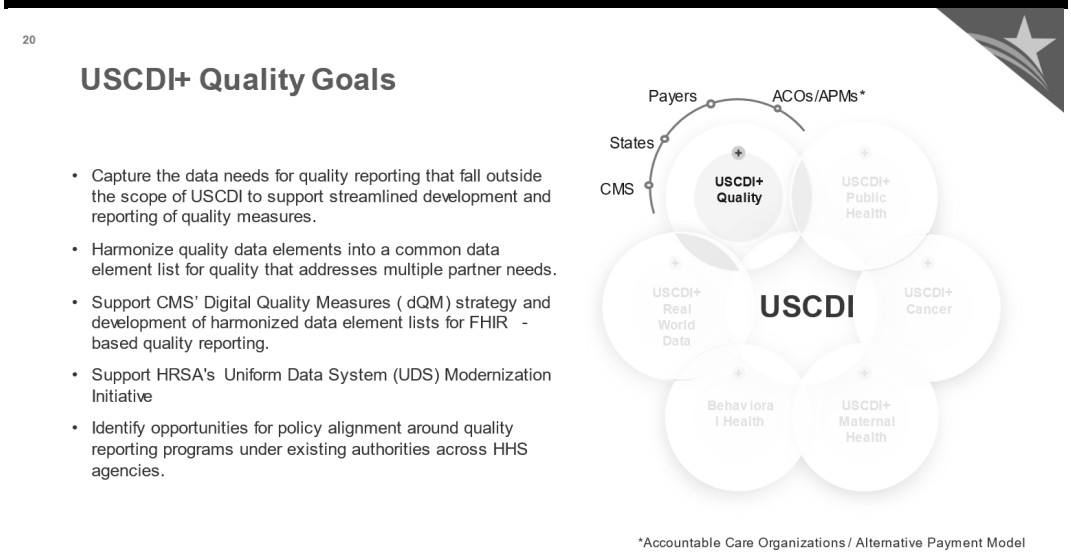


WAGNER: The data element list developed under USCDI+ will include multiple data concepts with underlying data elements and standards to meet program needs across HHS and allow outside entities such as technology and measure developers to harmonize in their future work, really with the idea to reduce the burden of data collection reporting and analysis. And then as you can see in this visual, we are looking to identify new data elements that are not included in USCDI but remain important for program-specific areas that want to ensure data element and standards harmonization.

[SLIDE 19]

WAGNER: So now we'll turn it to just looking at USCDI+ Quality and how that can be applied or implemented.

[SLIDE 20]

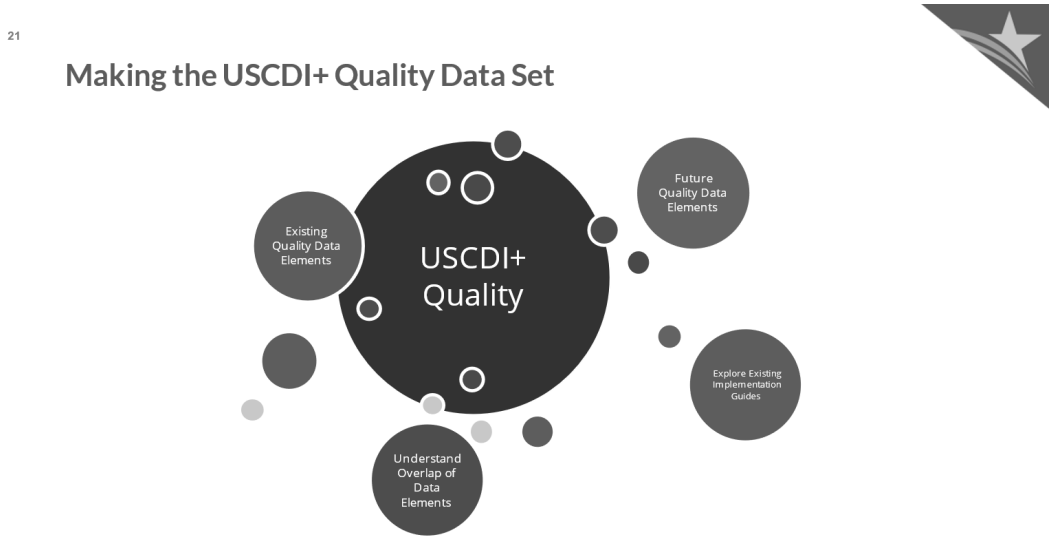


WAGNER: So for USCDI+ Quality, ONC, we started working with CMS and HRSA to identify USCDI+ Quality data elements. In particular our collaboration with CMS was around addressing core data and interoperability needs for CMS' FHIR quality reporting initiatives and Health IT certification which includes developing a future FHIR regulatory framework and certification model recommendations on use of FHIR Implementation Guides (IGs) and advising and supporting future policymaking and implementation of testing tools and resources.

And while quality measurement within CMS program is a key starting point, it is just one broader part of the broader USCDI+ Quality domain. We've also started engaging with a wider range of public and private partners, including AHIP and NCQA and NQF, all within the quality measurement space to support quality reporting, measurement and improvement. This initiative is identifying opportunities for policy alignment around quality reporting programs (QRPs)

under existing authorities at HHS agencies, and we're looking to support the collection and harmonization of quality measure data elements for the broader quality community, including specialty registries, payers, quality improvement organizations, and quality improvement models. As we continue to develop this data element list with clear clinical concepts mapped to data elements and standards, we're going to publish a final data element list for the quality community to support their work and align their approach to these interoperability goals.

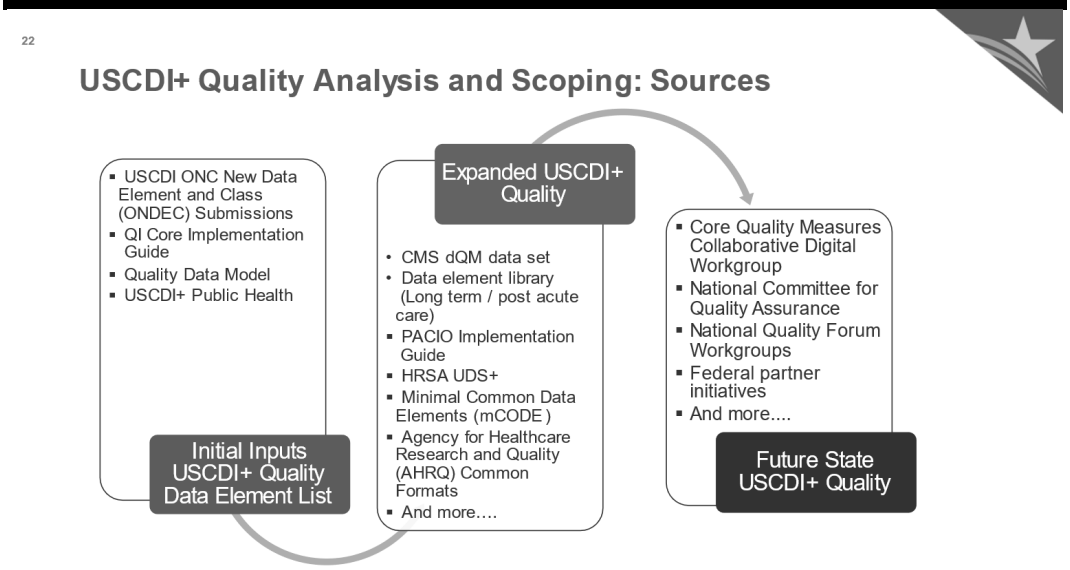
[SLIDE 21]



WAGNER: So the initial USCDI+ quality data element list builds on analysis and review of existing quality data elements, and the exploration of existing Implementation Guides (IGs). We're also looking at what's in the works with changes or updates to quality specific data elements. This is feeding into our

broader understanding of where there are overlaps and need for harmonization across quality programs.

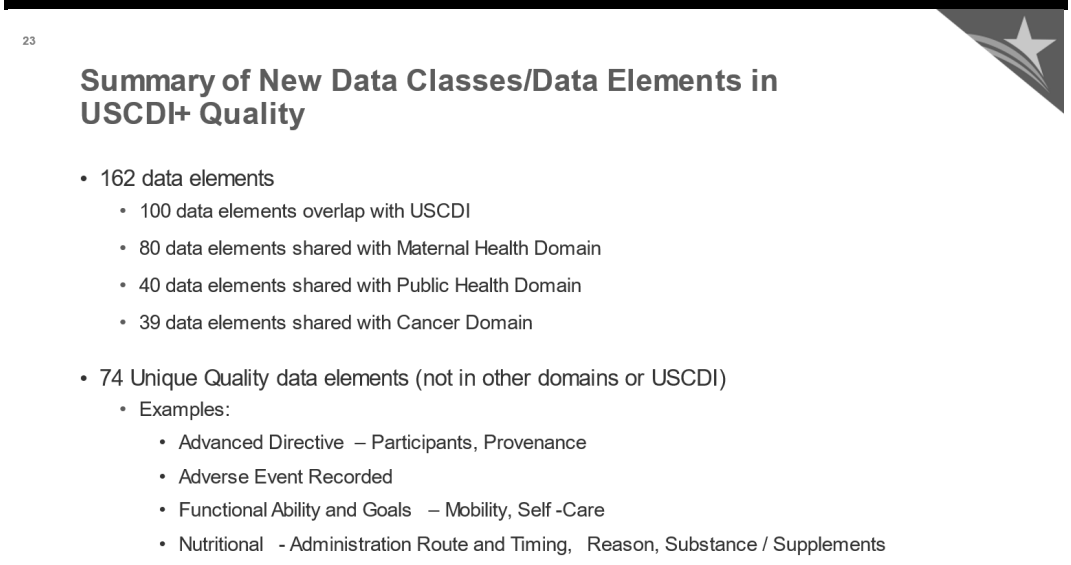
[SLIDE 22]



WAGNER: This is a little bit in more detail about where we started our analysis and where we plan to go. As I mentioned, we did start as a baseline of looking at USCDI and seeing where there are commonalities or submissions for USCDI that apply to the quality space. We also reviewed the electronic clinical quality measures (eCQMs) currently used in CMS' inpatient and eligible clinician (EC) quality reporting programs (QRPs) and data elements included in draft and published HL7 FHIR Implementation Guides (IGs) for different use cases, such as long-term and post-acute care, oncology, and federally qualified health center reporting requirements — particularly the health center reporting requirements that tie into HRSA.

We also had a series of discussion with other organizations, as I mentioned as well, to try to identify additional data elements that would fit into this quality data element list to identify high-priority data elements. Then we also looked at areas such as the Data Element Library (DEL) and our common formats, and we're continuing to explore additional areas to look including with comments from our partners that we received as a part of the first kind of public comment into the USCDI+ Quality data element list earlier this year.

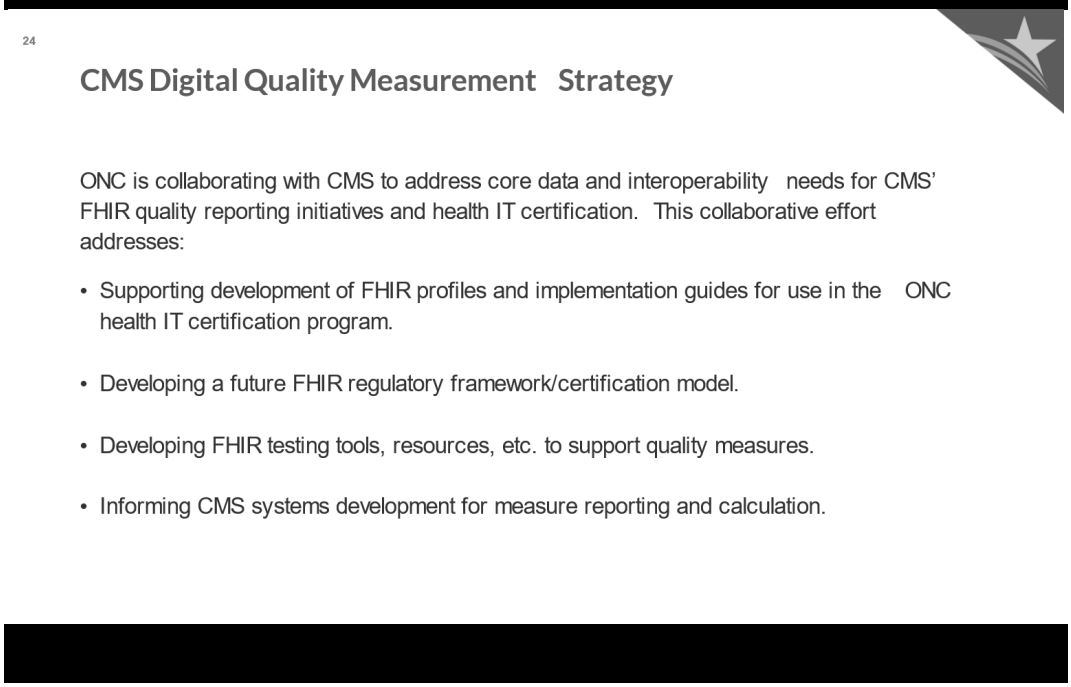
[SLIDE 23]



WAGNER: So just to give a quick snapshot of what is included in the USCDI+ Quality data element list, we published our version sort of .1 for public comment in May of this year on the eCQI Resource Center. It includes 162 different data elements, but a lot of those data elements really overlap with USCDI. We're also doing overlap in other domain areas for alignment and harmonization that needs to take place, but there are also unique data elements included in the USCDI+

Quality data element list, including a few that I've listed here around advanced directives, adverse events, and functional ability and goals.

[SLIDE 24]

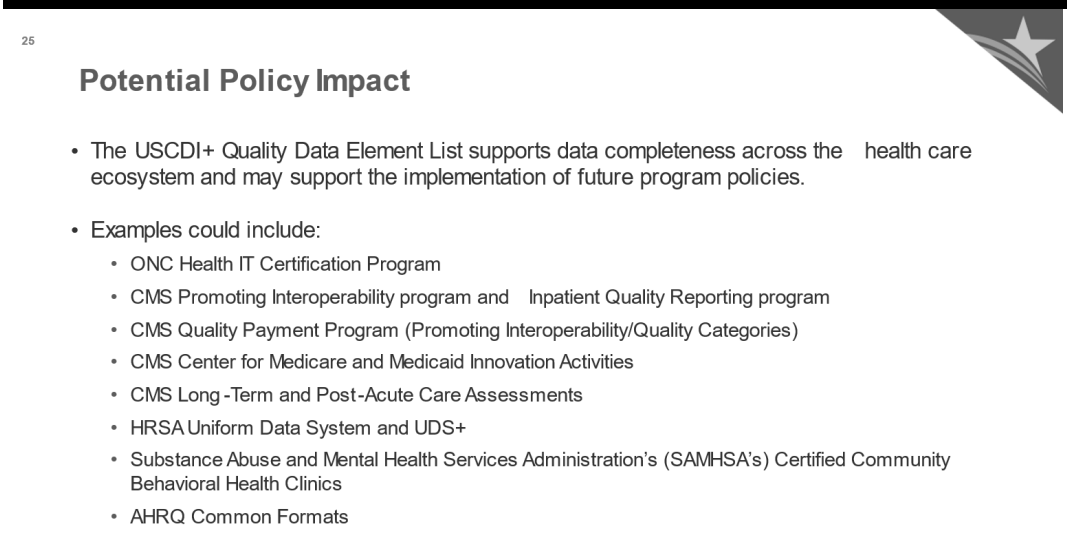


WAGNER: So the USCDI+ Quality initiative is intended to support CMS' digital quality measurement strategy as their quality reporting initiatives move to a FHIR-based model. The ONC certification program currently certifies Health IT for quality reporting capabilities under the CMS quality payment and hospital inpatient quality reporting programs (QRPs) for their recording and export, import and calculating, reporting and filtering of clinical quality measures (CQMs) through the conformance to the Quality Reporting Document Architecture or QRDA standard.

ONC and CMS are currently collaborating to develop the architecture for a FHIR-based quality reporting model which will include the potential development of FHIR profiles and Implementation Guides (IGs) that the ONC certification

program will measure conformance to, a new FHIR regulatory framework and certification model, development of FHIR testing tools, and other resources to support this new quality reporting framework. In this new FHIR-based model we are exploring alternative methods for measure calculation and reporting.

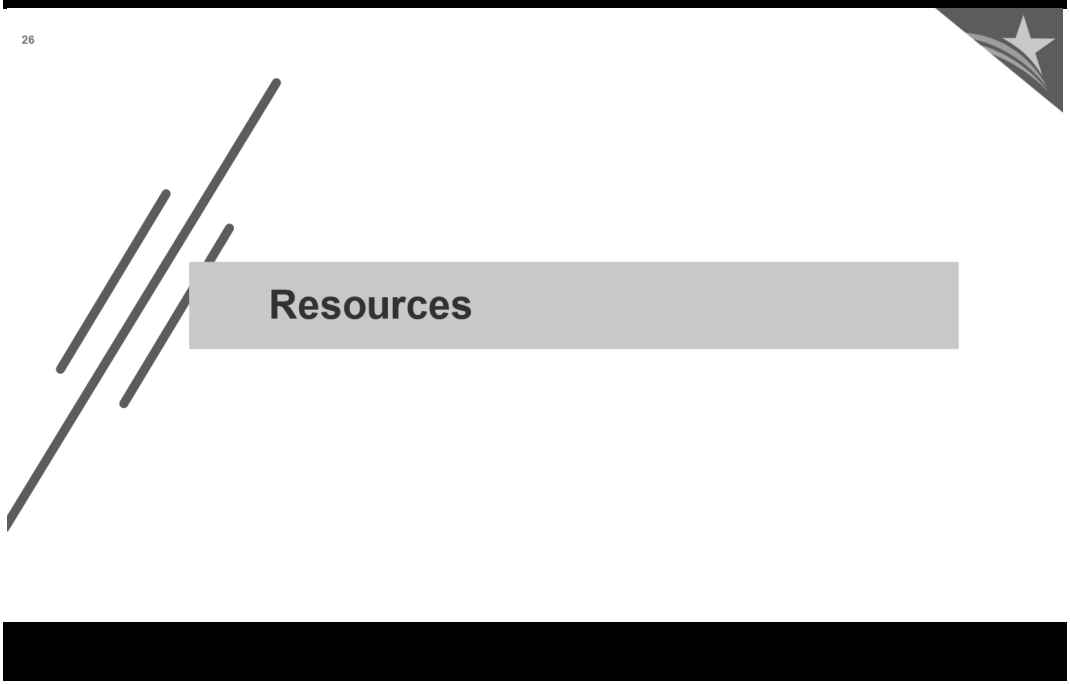
[SLIDE 25]



WAGNER: So just to say a little bit about possible policy impact. The USCDI+ Quality data element list is a policy construct that serves as a starting point for establishing a data model to support the exchange and use of data for quality measurement across programs, payers and care settings. Beyond our collaboration with CMS to support their dQM strategy, we are also working to discover and determine how USCDI+ Quality can be applied more broadly across programs at HHS. This slide includes some programs who have committed to moving along with the USCDI+ Quality model and some that we're still in conversations with about how to incorporate it and make it most useful, including sort of the SAMHSA and AHRQ aspects of it as well.

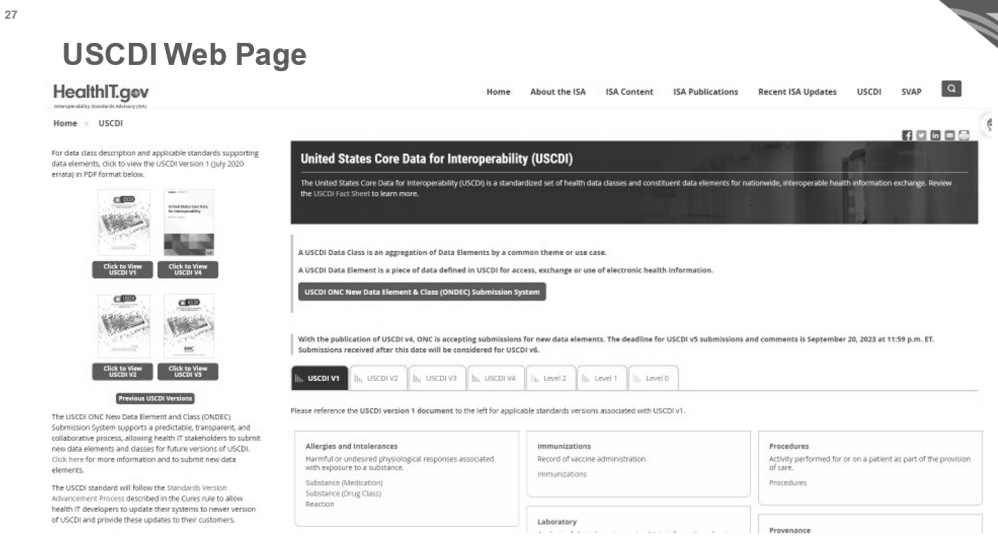
As we mature the USCDI+ initiative we will provide additional details on how new versions are developed and timelines for comments as this is intended to be a transparent process and allow for additional public input and comment into the process. So I think there will be more information to share once we have our next iteration of the USCDI+ Quality data element list available.

[SLIDE 26]



WAGNER: So just to close that out with a few resources that we've talked about today.

[SLIDE 27]



https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

WAGNER: There is the USCDI webpage which speaks to the work Al mentioned, and you can explore all of the current final versions of USCDI from Version 1 through Version 4 on that page. You can also look at all sort of "explore level 1, level 2, level 0," data elements that aren't currently on a final version of USCDI and see kind of where we had our starting point of all of the different data elements that have already been submitted into USCDI.

[SLIDE 28]

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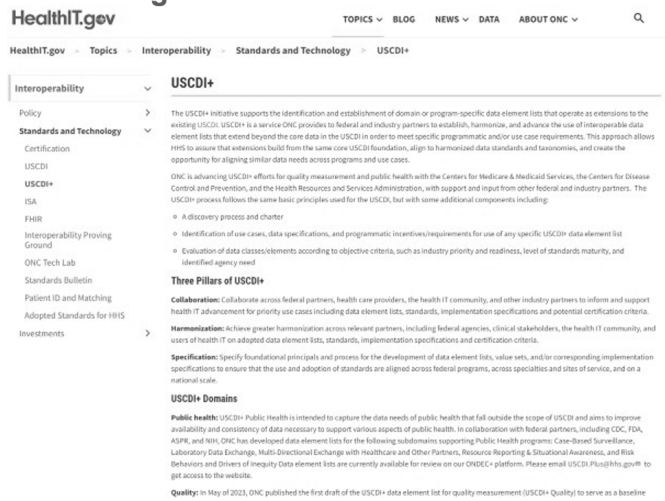
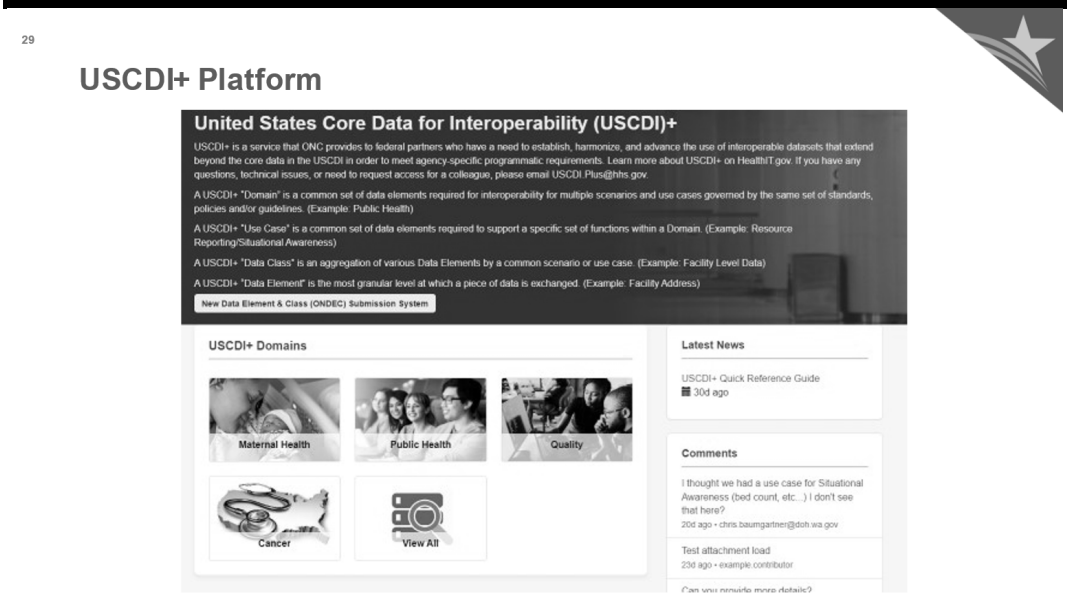
USCDI+ Web Page



https://www.healthit.gov/topic/interoperability/uscdiplus

WAGNER: There's also the USCDI+ webpage for you to explore. This webpage will be updated as we roll out the additional domains and have additional information to share about the additional domains, and then all of the links to any kind of comments will be included on this page in the future as well.

[SLIDE 29]



WAGNER: And then we're also building out a USCDI+ platform. For those who are familiar with USCDI, this is like our version of ONDEC submissions. The USCDI+ platform will house all of the domains that we're actively working on. So right now in this screenshot you can see quality, maternal health, cancer and public health. I think behavioral health is going to be added soon as well. This hasn't been officially launched yet, so stay tuned for more information about the official launch.

[SLIDE 30]

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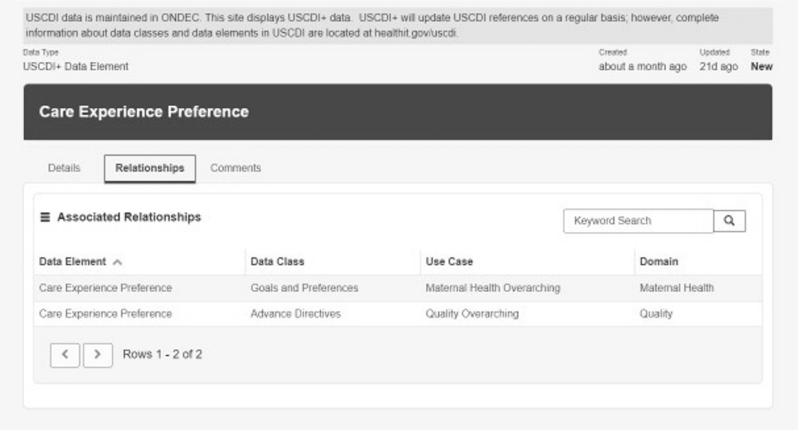
USCDI+ Relationships and Alignment

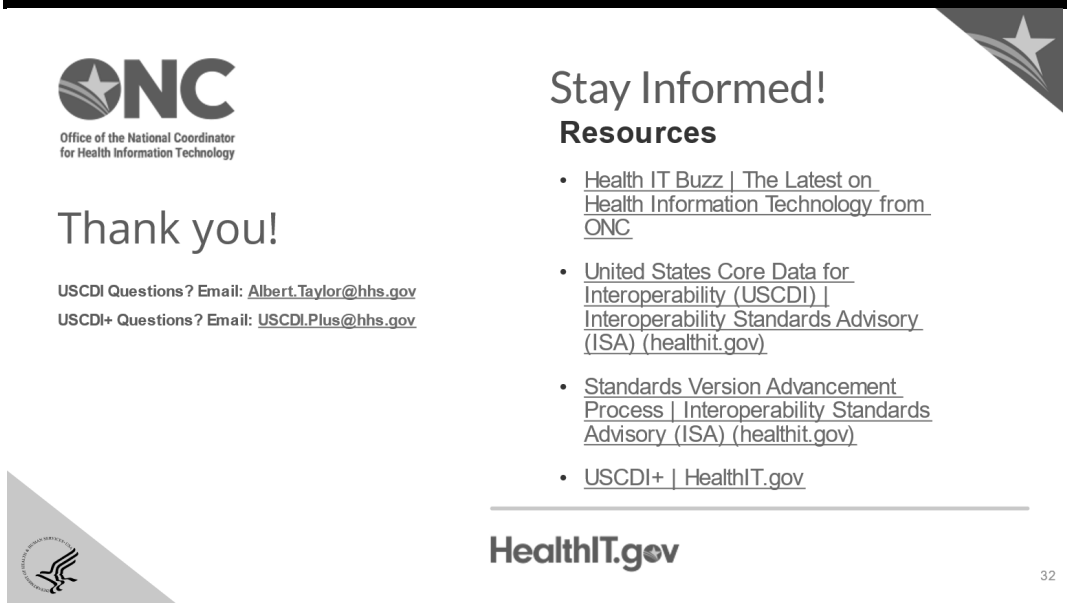


WAGNER: Just to show you that we're also looking at the relationships across different domains. So we have different data elements and they can be tied both to different data classes and different domains within USCDI+, but the idea being that we're all tying back to that same data element in an effort to capture more standardization.

[SLIDE 31]

WAGNER: And then here we'll give a little plug for those who are interested. The ONC annual meeting is taking place December 14th to 15th in-person in Washington, DC. If you're interested in joining us, please visit the URL here at www.ONCAnnualMeeting.com. We'd love to see you and we'd love to have you there. That's it.

[SLIDE 32]



WAGNER: Thank you, all. I think we're going to questions now, but I'll hand it over to Haley.

[SLIDE 33]
Q&A

Q: "Any consideration for USCDI+ with a pediatric focus?"

WAGNER: I wouldn't say that it's *not* being considered. So for maternal health I think one of our initial conversations was maternal and child health, and so more of an "MCH" lens. What we found is that that conversation was getting quite large. I think right now for maternal health we are going to have some infant kind of data elements, and so thinking through if there's an impact on the mother's health.

If there are particular data elements to consider and include, we are going to be doing that. I think trying to expand that out eventually is definitely a goal, but then it also gets into the question of what are we defining for pediatric, and are

we defining it as less than 18 years, or is it within a certain time period? So all of that is to say that it's something that we have talked about and considered, but right now we're focusing on sort of the maternal health piece.

Q: "What is the difference between USCDI and USCDI+ Quality?"

TAYLOR: Pretty much what we've been talking about for the last 30 minutes is that USCDI is a base. USCDI+ and USCDI+ Quality in particular is the delta between data that's required for everybody and data that might be necessary to participate if the scope to participate in amongst other things, the CMS quality reporting programs (QRPs). So the USCDI+ Quality is the delta between USCDI and what those programs might require or want. Is that fair, Lisa?

WAGNER: Right, I mean, USCDI is the base. It's our starting point and "quality" is more an extension of it. So USCDI, particularly the final versions aren't always going to have all of the data elements you might need for a quality reporting program (QRP). So we're trying to think through what exactly those needs are and building on the foundation of USCDI.

Q: "One suggestion for additional data elements for USCDI+ are those related to the CMS ESRD QIP program.
Is there material on how providers can assist with establishing a new domain similar to cancer, but instead for ESRD that CMS manages?"

WAGNER: So ESRD has come up in conversations with us related to quality. I think that we're open to conversations around what might be useful and important for USCDI+. I will say that a key component of USCDI+ — maybe this is

just common knowledge generally — is that ONC is a pretty small agency compared to CMS, or even HRSA or CDC. We have a tiny budget, and so a key part of USCDI+ is that we have partnerships and collaborations with other HHS agencies in particular who can help provide resources — whether that's both people resources and funding resources. That's not to say that those resources are only dedicated to that particular agency. The idea is being that it's holistic, but that there is some backing there from those agencies. So I think some of those conversations help to drive where we're focused, but we're open to having additional conversations. Like I said, we have had some conversations with CMS colleagues on the ESRD program, and I think there are potentially opportunities there around data mapping and what exactly is needed for the ESRD reporting.

Q: "Since USCDI+ won't have an Implementation Guide (IG), are there plans to close the loop and have new USCDI+ submitted to USCDI and included in the Implementation Guide (IG)?"

WAGNER: So I think this question is getting at that USCDI and USCDI Core IG are closely linked; though, I would not say that they're the same. Al, you're going to have to probably speak more to that, but I think what they're trying to get at is if there's no USCDI+ specific IG similar to US Core IG for USCDI, what does that sort of mean? There are a few different pathways in my mind, because we're also looking for at the end of the day how to implement, and the Implementation Guides (IGs) are a key part of that.

For USCDI+ it is possible. Like I said, a lot of times we looked at data elements submitted into USCDI. Some of them might be on a final version and some of them might not be. They might be at level two and sitting at level two ready to go, and maybe as USCDI slowly expands incrementally over time, that data

element that might be on a quality data element list right now does get added into a USCDI final version. If that's the case, then that would ultimately end up in some version of the US Core. Again, I don't think you can say USCDI and US Core are one-to-one, but they are closely tied.

Now for USCDI+ we are also looking at existing IGs. So there might be data elements on a final USCDI+ data element list that reference different IGs, but there might be some USCDI+ Quality that also have a number of data elements closely tied to QI-Core IG. That's some of the focus and work that we're doing with CMS on some of their digital quality measure (dQM) and move to FHIR-based quality reporting. So I think there are a couple of different pathways. I don't know, Al, if you want to speak more to the ties to USCDI and US Core IG which I think is what the person is getting at here.

TAYLOR: Yes, it sounds like it is related. I don't know if it's the same person asking, but it seems like it's related to a question that I just answered about "what are the chances that the USCDI+ data element could make it into USCDI someday?" So a couple of things. The answer to that question was if you haven't read it yet, things that are submitted for USCDI but not included in USCDI may be not included because it lacks some maturity in standards or it lacks a certain breadth of applicability to multiple use cases. It might make perfect sense to be in USCDI+ in one of the USCDI+ programs, but it doesn't meet the criteria for maturity and breadth of applicability to be considered for USCDI.

Should that change where standards mature and the data element is kind of reshaped or able to be expressed across multiple different use cases, we certainly would consider it for USCDI. So USCDI, a lot of the new data elements in USCDI don't already have a place in the US Core IG. That's what happens once

we publish the final version. US Core goes to work and the structured docs workgroup, working group works on the C-CDA updates it in order to accommodate these new data elements in USCDI.

So one of the criteria that we have for consideration for USCDI is, "is it reasonable to think that we can work this into the US Core or C-CDA Implementation Guide (IG)?" We estimate that ahead of time. We work with HL7 to refine that estimate. If it seems like a reasonable thing and it meets a number of different use cases — it helps with a number of different use cases when we consider it for the next version — then it will eventually get worked into an IG. We'll figure out a way. We work with HL7 to get it into an IG. So that same thing could happen with USCDI+ data elements that mature and reshape in order to be added to USCDI.

Q: "Is ONC also collaborating with CDC in standardizing quality data elements through its USCDI+ quality program?"

WAGNER: I think the simple answer is *yes*. ONC has had collaborations between CMS and CDC for a number of years, particularly with the national hospital safety network. I think that's what it is, NHSN at CDC. We've worked with colleagues there at CDC. We've also been working with some of their colleagues that are a part of their broader data reporting and policy work at CDC as well, and that's some of the harmonization effort that we've done between the quality and public health work of the USCDI+ domains.

Q: "Can you provide a few use cases for the USCDI+ platform?"

WAGNER: So for the USCDI+ initiative generally we have domains as like the broader—I mean, this comes down to nomenclature to a certain extent, but that's like the broader program area description. As I mentioned, that would be like quality, public health, cancer, maternal health and behavioral health. And then for each of those domains, some of them have specific use cases that we're working on. Ones that particularly stick out in my mind for like public health are around case surveillance, the use case.

For quality we haven't been as specific in defining use cases right now, but I will say that one kind of use case is some of the work we've done with CMS on their eCQM reporting efforts. And then the HRSA work as well on their uniform data system efforts to harmonize everything there. I think as we roll everything out in the platform everyone will be able to see kind of the final use cases, but some of those are still in discussion as well.

Q: "Who is held to these requirements or standards?
If not the EHR, it has limited impact."

TAYLOR: So the ONC certification criteria applies to Health IT products that certify to the ONC certification program. The certification program is a voluntary program; although, it's required for a lot of CMS programs to participate in their programs using certified technology. So it's one of those "you don't have to but if you want to do business with CMS" sort of thing. So EHRs are required. So EHRs can certify to the ONC certification program using their products. There are EHRs out there that have not certified but those EHRs can't be used to—well, perhaps they can be used, but I'd defer to CMS on this. I'm not sure if I'm saying this right, but you can voluntarily certify it through our ONC certification program for an EHR. That's who it applies to. There are requirements in order

to certify, and you have to continue to demonstrate an ability to do the things to certify, but it's "voluntary" to certify a product to our program.

Q: "Can you speak a bit about the rationale for USCDI elements also being included in the USCDI+ datasets rather than the plus sets being only additional elements?"
"Is there concern about the ability to keep the element requirements in sync as the USCDI+ versions expand over time?"

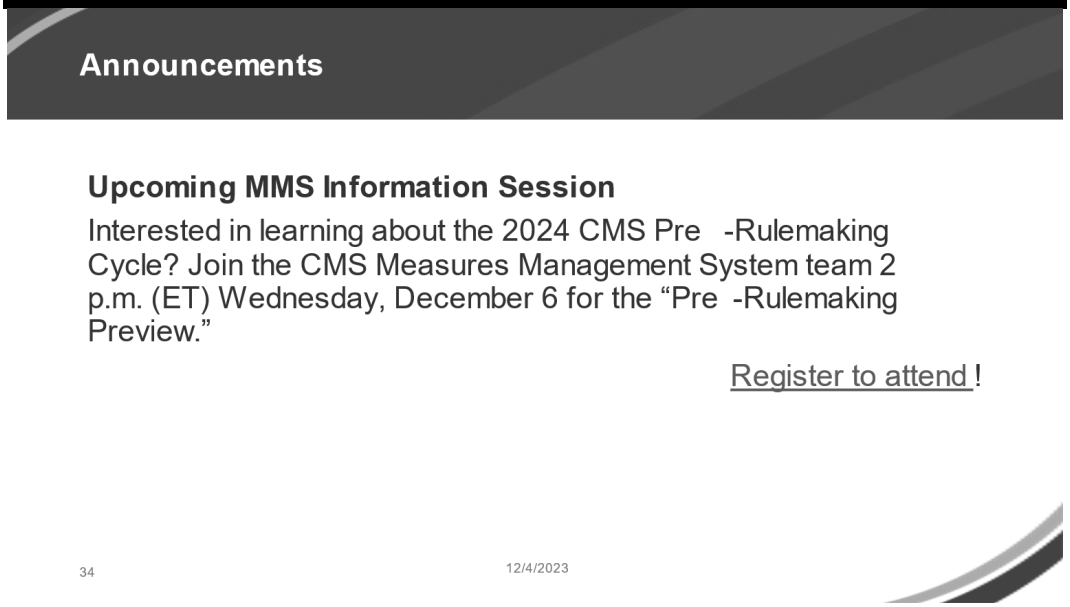
WAGNER: Yes, so this speaks to a system that perhaps we're humans and we're trying to keep up with both USCDI and USCDI+ updates. So to the second question, yes, I think that we have concerns about making sure it's updated, but it's similar to the concerns around when we update USCDI with a new version, and then making sure US Core kind of catches up to it.

I think the rationale for including specifically some USCDI data elements like being called out in USCDI+ datasets is that not all USCDI data elements are as maybe closely tied or important for specific domains in USCDI+. So I've even asked this question before to ONC in that do we really need to do that? I think right now our thought is that we're trying to call out specific USCDI data elements that are critical to that domain. In theory, if it's an extension of USCDI, we are already saying all of USCDI is included, because of already existing program requirements and everything else.

Now, getting to that point of if it's cyclical and we're trying to always make sure we're keeping up with USCDI as we're updating USCDI+, that gets into the process of things and I can't say none of that will change over time as we're working through all of that.

VON HOLST: All right, thank you. I think that was all we had time for in terms of questions and answers (Q&As), but I really appreciate all the engagement. These were great questions from the group and always brings a lot of value to these discussions.

[SLIDE 34]



VON HOLST: We hope you'll join us next Wednesday at the December 6th session for our pre-rulemaking preview. As always, please visit the CMS MMS Hub to stay up to date on all of the latest MMS news, events, and quality measurement resources. Again, this recording will be posted on the MMS Hub later, but we have distributed the link to the slides for now. We look forward to seeing you next week and thank you for attending. Also, thank you so much to Lisa and Al as well and appreciate you both very much.

[SLIDE 35]

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