BJA's Comprehensive Opioid Abuse Program

PODCAST SERIES TRANSCRIPT

PDMP—21st Century Cures Act

Announcer: Welcome, and thank you for listening to this recording, part of the Comprehensive Opioid Abuse Program (or COAP) podcast series. COAP provides financial and technical assistance to states and units of local and Indian tribal governments to plan, develop, and implement comprehensive efforts to identify, respond to, treat, and support those impacted by the opioid epidemic. Since 2017, BJA has supported innovative work on these COAP sites across the nation.

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Jim Giglio: Welcome. I'm James Giglio, Senior Program Coordinator with the Prescription Drug Monitoring Program Training and Technical Assistance Center, better known as TTAC. TTAC is located at the Institute for Intergovernmental Research and funded through the Bureau of Justice Assistance. TTAC provides a comprehensive array of services, support, resources, and strategies to PDMP's Bureau of Justice Assistance COAP grantees, federal partners, and other stakeholders to further the efforts and effectiveness in PDMP in combating the misuse, abuse, and perversion of prescription drugs. Our focus is to improve consistency and alignment among PDMPs, facilitate coordination between PDMPs and state and national stakeholders, increase PDMP efficiencies, measure performance and effectiveness, and promote best practices.

This podcast will cover the 21st Century Cures Act, data exchange standards, and information blocking. The moderator is Patrick Knue, Director of TTAC. Pat is joined by Elisabeth Myers, the Deputy Director, Office of Policy, at the Office of the National Coordinator for Health IT. Elisabeth Myers has worked on health IT policy at the Department of Health and Human Services since 2012, working on CNS quality programs, the CNS eHealth initiative, and EHR incentive programs, before moving to OMC. Prior to her work at HHS, Ms. Myers worked on health-care initiatives in the nonprofit and private sector and at the state level in the Governor's Office of Health Care Reform in Pennsylvania.

In her role at ONC, Ms. Myers is helping to lead the team implementing the provisions of the 21st Century Cures Act, which addresses a wide range of health IT provisions, from interoperable standards development to health IT for specialty settings and sites of service. She will also be leading the team at ONC for efforts related to the health IT provisions within the Support for Patients and Families Act, which was signed into law in 2018 to drive policy initiatives in support of opiate use disorder prevention and treatment. I will now turn it over to Pat.

Pat Knue: Well, thank you, Elisabeth, for joining us on this podcast on information blocking. I'd like to get started with some preliminary questions. Most people know that ONC stands for the Office of the National Coordinator for Health IT, but who is ONC?

Elisabeth Myers: Sure. So thank you for having me. Who is ONC? I'll do who is ONC first and then mention who I am at ONC so there's a little bit of context for everyone. ONC is the office within the Department of Health and Human Services. We are actually in the secretary's office, but we have our own political leadership, and we have our own statutory requirements that sort of establish who we are and what we do. Those include things like serving as the coordinator for standards across HHS, but also across the federal government if it's a standard that relates to health information technology and health information exchange. We run a certification program of health information technology that was originally established to support what is affectionately known as the Meaningful Use program, or at least historically was, but has shifted in recent years to be about promoting interoperability, and it's called the Promoting Interoperability Programs, which are CMS programs related to the use of health IT by health-care providers in a variety of settings.

That certification program also supports things like alternate payment models, some of the state programs that states might have for Medicaid participants that are providers that are engaged in public health reporting or in health information exchange at a health level, and we also support a wide range of innovations around standards and health IT adoption and use. That's sort of a cusp of what we do, in a nutshell, and the way that we do that is multifold. We have a structure to our office that supports our ability to support both health IT in practice and standards developments as well as looking at policy and health IT policies across a nation and how they are moving health care forward.

One of the things that we have done is sort of structure our organization to sort of meet that end. We have an overarching front office. That includes the number of clinical team staff that help with giving us the provider perspective from a number of different provider viewpoints, including hospital view, clinician view, and a scientific and research point of view. Then, we have two branches to the Office of the National

Coordinator that sort of operate hand in hand but manage different aspects of how health IT is approached across the nation.

One is our Office of Technology, and they look at standards and standards development, but they also run our certification programs. So they're looking at those two things together. They're both reviewing ongoing standards and emerging standards as they are developed through standards development organizations, and they publish what's called the Interoperability Standards Advisory that captures that information and allows for public input on that information. Then, they also implement what comes after regulation around standards, which is our certification program that, again, supports CMS programs, state programs, and other federal agencies in terms of how health IT is actually implemented in practice.

On the other side of the office, we have our Office of Policy. That's the shop that I am in. My team works on a variety of different pieces as well. We have a group that does strategic planning. That group runs things like our federal advisory committee reports to Congress about our progress on various statutory requirements for health information technology. They report out on the progress towards specific Health and Human Services departmental goals. They also provide feedback and context for us about things that are going on with the broader picture of health information technology. Our Regulatory Affairs division, which writes all of our policy regulations and also helps to support other federal agencies, specifically other HHS agencies, in their regulations when their regulations touch on health information technology. That team's actually responsible for making sure that we support those other agencies when their regulations need to rely on our regulation or when they have to meet certain goals that align with [inaudible 00:07:50] legislation that ONC is responsible for.

That team also writes our regulations based on what Congress comes through and actually identifies ONC's role within the federal government. We'll talk a lot about that today, because that's actually the impetus behind our current proposed regulation for the 21st Century Cures Act, which you mentioned at the top. I'm going to mention one more team that is part of that policy office, because they play an important role that sort of connects all these dots. They're our Interoperability Division, which is a really big and broad name, but they do a lot of implementation work. Actually, most of your audience may know some folks on that team. That team does a lot of work with states. They've worked on the SIMS states initiative. They've worked with state Medicaid agencies. They've worked with public health and public health agencies, including our PMPs. They also work on sort of a broad look at the care continuum, thinking about long-term, post-acute care, behavioral health, opioid use disorder treatment and prevention, pediatric health IT.

So that team is involved in a lot of projects that are very hands-on, either pilot work that is going before a regulation happens or helping to implement and provide technical assistance to states, health-care providers, regional information exchanges, and actually implementing the policy work that comes out. It is a really small office overall in terms of federal agencies, but it's a really mighty one. We do a lot of really exciting work. One of the best roles we get to have is working with stakeholders and trying to get their input incorporated into the process and making sure that their needs are met by the work.

Pat: So you mentioned it during your response there, but what is the 21st Century Cures Act?

Elisabeth: Sure. The 21st Century Cures Act is a law that was passed by Congress late in 2016. That act is a really broad look at health care. There are pieces in it that relate to NIH and some of the work that they do and FDA and some of the work that they do. But there was an entire section on it, Section 4 of the Cures Act, that specifically talks about health IT. It has more than a dozen subsections in that title. Sorry, that is Title IV of the Cures Act. It has these sections that relate to health IT across a wide range of policy constructs. So I'm going to talk about quite a few of them today, because they're fairly relevant for PDMP administrators and for states and those involved in public health, in general. There are specific ones that we addressed in this proposed rule.

If you're looking at a law, this is a really big one, but it's an interesting one to take a look at. There's a number of folks on our team who sort of geek out on this type of thing, but I understand that sometimes it seems a little more daunting for the public. Title IV is divided into these sections. Section 4001 specifically looks at health IT across a care continuum. It talks about burden reduction. It talks about pediatric health IT. So it's sort of focused on this idea of making health IT more usable for providers in a wide range of settings, and that's kind of how the law works, in general. Each section sort of has a theme that Congress identified as a group of policies that go together. Then, from there, what we do is look through that law and identify what we're required by Congress to put into legislation.

So the pieces of the 21st Century Cures Act that we have specifically addressed in this regulation are, there's several, but I'll sort of go through them one by one. Section 4001, which, again, talks about health IT across the care continuum and reducing the burden on providers. You may have seen one thing that we did several months ago was put out a public report that we sought comments and feedback from stakeholders that talks about burden reduction. That is specific to Section 4001. That section includes a conversation about how health IT can reduce the burden, but also, how can we improve health IT so that it doesn't cause additional burden on clinicians? It included information about EHR reporting, public

health, billing and coding, documentation, all sorts of things that were covered in that that were defined by the law.

The other pieces of that section talk about health IT on a broad spectrum across the care continuum. It includes pediatric health IT, so that's one of the pieces that we're specifically addressing in the rule, is looking at how we can better support the actual on-site implementation of health IT in a way that meets the needs of pediatric health-care providers, so specific things they care about, like safety and certain preventative care initiatives that are relevant to pediatric settings.

Section 4002 is called—we call it the conditions of certification section. This is a really interesting section, and I think this is a section that this audience might find of particular interest. The conditions of certification include several policies that are sort of an expansion of how health IT policy was previously looked at, in the federal sphere, at least—the previously ONC certification program, and specifically designs around supporting the needs of specific CMS programs. It changed over time to be a little bit more flexible and have those modules work a little more broadly, but in large part, the entire authority boundaries for the program were on those specific criterion and those specific program needs.

What the conditions of certification in the Cures Act does, it goes a little bit broader and talks about as a condition of being certified, of a health IT developer being certified to a specific criterion or function; there are other things that they should also do. Those things might include business practices and behavioral practices that sort of go beyond just building the technology in a certain way. They include information blocking, so you can't be blocking information from flowing freely. It includes assurances, which is essentially the assurances that you make about what your product can do, things like privacy and security, your assurances about how it will function, who owns data, those types of things. It includes how you communicate about your product and that you're giving up-to-date and relevant communications, especially about things like breaches or errors in a product. It includes application programming interfaces, which I think we should talk a little bit more in depth about, because I think this is a specific thing that might be of pretty big interest to PDMP administrators for some future development opportunities there.

It also talks about real-world testing of certified health IT, which I think is an important point, again, for this audience, because this is the first time that we've been able to look at what happens in the real world, right? What happens in real life. It's all well and good to pass a test in a lab, but then, when you actually go to implement that thing, there are all sorts of other factors that impact how well it's going to work. They might be other policy factors, like the differences between state and local laws to the federal law. It might be what types of mix of products you have in particular settings. You might have three different vendor products in a

particular setting. So what real-world testing does is allow us to require, as part of the certification process, that developers actually have to have a robust real-world testing plan that is part of their certification process that shows that they are, in fact, testing and adapting the product as appropriately needed for each setting.

Then, there's also some attestations that they have to do that are sort of sworn statements about various things about the product that are part of that section of the law. So it's a really important section of the law, and we think it's a really useful thing. It's one of the things that we've spent quite a lot of time and pages on in our proposed regulation. I'm going to go through some of the others really quickly.

Section 4003 is specifically talking about the definition of interoperability. Congress actually defines what they mean by interoperability in this law, and that's very important, because when you look at state laws or other programs, if everybody has a different idea of what's going on, it means that we're not necessarily agreeing with what we actually need to be accomplishing. So Congress setting that in this law is an important level setting for all of us about what we're really talking about when we say interoperability or require interoperability.

Section 4004 is information blocking. I think we should talk a little bit more about this later so we can get into a little bit more depth. For right now, the important thing to understand about what's actually in the law on information blocking, Congress defines what information blocking is in the law. They make a statement that defines how the law views information blocking. Then, from there, they define, sort of broadly, what actors this definition is applicable to. Then, they set the authority for who has enforcement authority on it. We can talk a little bit more about some of those enforcement provisions. Broadly, what [inaudible 00:17:44] put into law is that the Office of the Inspector General has first-enforcement oversight. Then, ONC has some authority over health IT developers. Then, broadly, HHS would be required to have disincentives for health-care providers who are engaged in information blocking.

The other thing that the law does, and this is a big part of what's included in ONC's proposed rule, is it says that ONC actually has to define what an exception to information blocking is. This is a really big difference between the 21st Century Cures Act and HIPAA. The 21st Century Cures Act explicitly makes this assumption that information is moving. So the definition of information blocking is anything that prevents information from moving. HIPAA is very much a permissive thing. It tells the occasions under which you are allowed to send and disclose information. So that is a different sort of construct there. In the law, Congress defines what information blocking is. There's an assumption that information is moving. Then, it gives ONC the authority to set exceptions, which would be the reasonable things that one might be considered in order to not be treated

as information blocking. That's just a really important distinction in the law that I think is of a lot of interest to a lot of folks, but we've tried to capture in the rule what we think those reasonable exceptions should be. We can talk a little bit more about those, too.

The other two sections that I sort of wanted to mention, because I think they'll have some relevance for this audience, that are part of the 21st Century Cures Act, Section 4005—and I know, again, I'm speaking legal speak again here. Again, remember, each section sort of deals with a specific area or specific concept. So Section 4005 has some things that address safety, but the other piece that it has is this idea of health information exchange with clinical data registries. It doesn't specify that we're just talking about a qualified clinical data registry. It's very broad. It talks about registries in general. So what we've done in this proposed rule is actually have a request for information. It's an RFI is the acronym that you'll hear us all say. It's a request for information about how data is exchanged with registries, what types of certifications, standards, and criteria can support exchange with registries. In this case, we're specifically talking about bilateral or bidirectional exchange, which are sort of different things.

What we're talking about here, we want to make it as broad as possible to try and get as much information as we can. So we want to hear from public health agencies in addition to clinical data registries, in addition to providers, in addition to health IT developers on that RIF. We can talk a little bit more about some detail about what's in there. That, I do think, is an important piece for this audience.

The other last section I want to mention is that there is a section that talks specifically about patients' rights of access and giving information to patients in a way that helps them understand what they can and can't do, but it also thinks about the way that providers understand how information can be shared with patients. Section 4006 specifically talks about how to engage patients and help patients understand how to engage with their own health information. We have some proposals about making sure that patient's data is available to them, but we also have a whole bunch of resources that support patients understanding how to access their information, what they can do with their information. We have a consumer guide called *Get It, Check It, Use It* that's out there that helps to support this information as well. That may not be one-to-one correlated with your target audience and with PDMP administrators, but it's a really important dynamic of how patient information moves that I think is relevant to the overarching construct of the type of work that you're doing and understanding how it relates to what patients understand about their data and their PDMP data.

So I wanted to point that one out. That, in a nutshell, is the major portions of the law that are included in this. I could probably go on for another 20

minutes about the rest of the law, but we'll try and keep it a little more succinct from here on out on what's in the regulation. That's sort of the overarching law.

Pat: Great explanation overview of all the proposed regulations, but what does ONC intend to accomplish with these proposed regulations?

Elisabeth: Sure. I think the purpose of this particular regulation, obviously in addition to meeting the statutory requirements—I should note that the statutory requirements aren't the beginning of this process. We had a lot of input and technical assistance into the making of the law. Obviously, these are the types of things that we've been working on for years. What we're really trying to accomplish with this rule is sort of setting the next stage, setting the next level. It's setting the next level for new standards and how the standards can be supported in a wider range of health IT. It's setting the next level for our baseline for how information is exchanged, to try and open up the channels by which information could be exchanged, and to sort of set the next level of ensuring that there is access to information where and when it's needed. That's a real big primary goal here.

Interoperability isn't about making machines talk to each other. It's about making sure that the people who need the information can use it. So that's really the sort of top and primary goal of this particular proposed rule.

Pat: A lot of folks that TTAC works with are with the prescription drug monitoring programs. Does the regulation have an impact or effect on the PDMP operations? What part of the regulations would be relevant for the PDMP administrators to know?

Elisabeth: Sure. I think there's a couple things that are going to be pretty relevant and important. One of them is that API that I mentioned. As we know, across the country, PDMPs are done in a lot of different ways, even when they're sort of starting from the same product or a same service provider. The nuance in how that's actually happening is very complicated, to say the least. I'm sure that everyone listening is more than a little bit aware of that. Some of the technical pieces that are included in this rule could help to facilitate some of those challenges. First, we are proposing an update to the scripts standard. The new version of the electronic prescribing script standard does allow for a wider range of transactions, so that's a really important point and something to take a look at that could potentially support more fluid movement of the type of data that PDMP is concerned with. That could facilitate easier exchange, less translation required, and, hopefully, make it a little bit easier for that data to flow from provider to pharmacy to PDMP and back again. So that's one piece to take a look at.

The other piece that I think is particularly relevant for those who are interested in figuring out what's next for PDMP operations and what could be next for your next review of your technical contracts and technical requirements, and that's the application programming interfaces. In the 2015 addition, ONC had proposed and adopted a criteria for application programming interfaces. What that means is that we added a piece to the certification program that said, "All health IT developers that are supporting providers broadly have to have an application programming interface." For those who haven't been spending too much time in this world, an application programming interface is also called an API. It's essentially a portal. It is not a portal like you think on where you log on to a Web portal, but a portal like a window on a ship. So you have a room full of data or a ship full of data, and this portal allows for you to have a controlled access to that data that is not document-based. It could be document-based, but it does not have to be.

It essentially sets parameters and rules that say when someone comes and knocks on that window, you can open it and provide them the information that they're asking for in a really easy way. You don't have to package it and ship it off in an envelope. You don't have to build a one-off technical requirement. You've built this API that has certain rules around it, so the person coming in knows those rules and meets them and can pull out the data. So it allows for this sort of efficient but structured transmission of a wider range of data more easily than prior versions, where you might have been sending a document that might have to be translated twice and then reincorporated and might have a human who then has to review it a hundred times to see if each piece lines up appropriately and has some of those types of challenges.

So we had this very open application programming interface that we were requiring to be a part of the tech. At first, the use case was to try and allow patients to have access to that. In that case, you're specifically thinking about someone using their smartphone to—you know, Apple, for instance, has a product that does this, to pull up their health information. A lot of developers have this, beyond Apple, but that's just one that, in particular, is one that people are very, very familiar with and could use on their smartphone. That was your initial use case. From there, what we've done in this proposed rule is said, "Okay, now we've got APIs that are starting to be out there for that particular use case, but the potential for APIs is much, much broader." The potential for application programming interfaces goes beyond just patient looks something up on their smartphone and really thinks about how we're exchanging data full-scale across the health-care system.

So what we've done is proposed a broader application programming interface that includes a standard for how that is built. So instead of just being any API will do, we're now proposing that it should be a FHIR standard. If you haven't heard of FHIR, it's a standard for application

programming interfaces specific to health care that is run through HL7, standard development organization. They've actually most recently released a fourth version of this particular standard, but it's been out there for a while. Version 2 and Version 3 are actually in active use. So that particular standard allows for health-care data constraints around how the API is moving the data. It has a series of resources that allow you to move different types of information based on different types of use cases. So we've proposed to use that in this rule.

We've also proposed certain things around behavioral practices, saying things like you can't be discriminatory in who you allow access to that API. You have to be responsive to requests on that API. Then, how the tokens and refresh tokens on that API function so that we can actually support provider-to-patient exchange, but also provider-to-provider exchange and, potentially, provider-to-x, other entity. It could be a health information exchange. It could be a clinical data registry. It could be a public health agency. It could, for instance, be a PDMP. Right now, obviously, you're getting that information from pharmacies, but there is the potential that you could use this type of technology to aggregate information in different ways. So that's one thing to keep an eye on and to certainly comment on for us and think about how that could work.

One of the really exciting things about the Fast Healthcare Information Resource, FHIR, that is unique for the fourth iteration of it is that it can think about bulk data. So instead of just moving a single patient record from place to place, it could actually move a pool of patients through the API in a structured and safe and secure manner. So that's one thing that I think is particular of interest for PDMP administrators to keep an eye on and take a look at, especially as you're thinking of future builds and potential innovation for future builds and how you might rethink some of the current challenges that you have in how you're exchanging information in these translated documents.

Pat: You mentioned earlier information blocking, a request for information blocking on the opioid use disorder prevention treatment. Can you go into a little more detail or explain exactly what that means?

Elisabeth: Sure. One of the RFIs that we have included in this proposed rule—I did mention, in detail, the request for information about Section 4005. What we also have is a request for information that relates to Section 4001 that I mentioned earlier. I know that Section numbers are not helpful, but again, if you do look at the laws, it's easy to sort of see them in little packages. Section 4001, again, deals with the health IT for the care continuum, pediatric health IT. There's a question in there that talks about what other settings or use cases should ONC be taking a special look at. The request for information on opioid use disorder prevention and treatment—very long phrasing there, but we're trying to cover the baseline not just of PDMPs, that electronic prescribing of controlled

substances, but also how health IT can support care of patients who have opioid use disorder.

So we've asked a number of questions in that particular section. Again, RFI means request for information. It is not a proposal, so it is not saying this is new required policy or this is something you'll have to follow or adopt immediately. Instead, we're asking a series of questions that specifically are looking at what is the current state of health IT, what is the current state of our proposed new health IT versions, and how does that relate to the work that's being done nationally about opioid use disorder prevention and treatment, including, for instance, PDMPs and the work that PDMPs are trying to accomplish, some of the challenges that they face, and how health IT could potentially facilitate that, including, again, things like our proposal and the application programming interface.

Proposals on new standards and proposals on how real-world testing might potentially support things like making sure that when a developer implements technology in a real setting, that integration of a PDMP and that interface are adequately included in the workflows, both from a technical and an implementation point of view, to sort of reduce the burden on providers, but also ensure that PDMPs are actually being leveraged and used. If it's too different, we've found that it's not being used appropriately.

So we do have that request for information in there. I strongly recommend—actually, we'll put in a plug and call it a flat-out request that the PDMP administrators and those listening to this program take a look at that. It's only a few pages, so it's not a hugely dense piece of information. Please do comment back and give us some detail on your thoughts on that particular item in the rule. We will absolutely read it and take it into account. What a request for information in a rule does—as I mentioned, it does not set policy, but what it does do is inform future policy. So that particular request for information could help us to figure out what we might do next, but also what our partners might do next.

A lot of this work is housed at CDC or at SAMHSA or at CMS with various models and programs and state waivers. The work that we do on health IT and the information that we get from you all on that request for information can help them understand the technical provisions that go along with their broader policies in this area.

Pat: You touched on this earlier, and forgive me if I ask you to repeat some stuff, but the Cures Act does define what information blocking is. Can you explain how that's different from HIPAA, from something like HIPAA?

Elisabeth: Information blocking in the Cures Act is specifically defined to essentially state—I'll actually just go ahead and say it all out loud, and we can talk a little bit more about pieces of it. Information blocking is a practice by a

health-care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. So that definition is what is in the Cures Act as what information blocking is. We mentioned this a little bit earlier, but as your question implies, there is a difference between that and how HIPAA functions.

HIPAA is a set of rules and governance around what is an allowable exchange of information. What it doesn't address is what happens when you run into a reason to not send that information that goes beyond sort of the very basic. For example, in HIPAA, you are allowed to get patient consent to disclose the information for certain purposes. You are not, in fact, required to get patient consent beyond a certain reasonable attempt. The information blocking definition in the Cures Act is quite literally saying that except as required by law or specified by the secretary as a necessary activity, that any activity that is interfering with preventing, materially discouraging access, exchange, or use of electronic health information is information blocking. Again, the assumption is that the information is, in fact, being moved unless a law or a reasonable and necessary activity prevents you from doing so.

So it's important to understand that context, that you have to actually meet one of these exceptions or have, potentially, a state law like [inaudible 00:37:07] 42 Part 2 might impact this. Laws around privacy for information for minors state to state might impact this. Otherwise, it is, in fact, saying that you would have to meet an exception in order to be allowed to not share that information.

Pat: Now, Elisabeth, what types of information are we talking about?

Elisabeth: Sure. There's a definition about what electronic health information is, so we should probably start there, that electronic health information is what we're talking about. There's a reason that we're specifically talking about that, because it's really dealing with information that is transmitted or maintained in some form of electronic media. We're not saying that you have to magically figure out a way to send 20 years of historical records that are all paper-based that have never been translated immediately on a dime. That's not what's being talked about here. What we're really talking about is electronic health information that is electronic protected health information, which is a HIPAA definition that says it's information transmitted or maintained in electronic media that may identify the individual or with respect to which there is a reasonable basis to believe the information can identify the individual—and that's an important distinction within HIPAA, that it's not just a name, but also that if the information taken together could easily identify who that individual is.

That's an important point. That relates to their past, present, or future health or condition of an individual, the provision of health care to that individual, or the past, present, or future payment for the provisions of health care to an individual. That's a bunch of things together. Yes, I was, in fact, reading—I know it sounded like it—to make sure we got each of those details right. So it's really talking about that bucket of electronic health information that includes the individual's demographic information, identifiable information, their health history, and their current health condition, any procedure or lab or that type of information that relates to their care that they've been given, and then things that might relate to the payment for the provision. A lot of times, there might be particular claims data that is additional, because maybe that's what was stored from a prior record or from a transition. If that information is held as electronic media by the provider or health information network, that is part of what needs to be transmittable under what we proposed for our electronic health information definition.

Again, I do want to make very clear, all of these things are proposals. So we do welcome feedback on them, and they could potentially be adjusted based on public comment. That is the total sort of package of information. I want to make really clear, too, that we're not talking about information that is created by the health provider, right? It could be information they've received from another source. It could be information from a health information exchange that they've aggregated. Each of those actors is independently accountable to make sure that that information is moving. Again, their actors are health information exchanges, health information networks, health-care providers, and health IT developers of certified health IT.

Pat: Great. Thank you for explaining that. I'd like to end with if someone becomes aware or suspects someone's attempting information blocking, what procedures are in place for reporting this?

Elisabeth: Sure. So it's going to start with a complaint process that directs the national coordinator to have a standardized process for the public to send it reports. We do have a page on our website that is already doing this, healthit.gov/healthit-feedback. So you can take a look at that website, and you can see the information that's already available there. I do want to make very clear that the actual investigation authority under the law is with the Office of the Inspector General. Generally, the way that it would work is that if one of the actors—again, the actors are a health information network, a health information exchange, a health-care provider, and then health IT developer of certified health IT. If any of those actors is suspected of information blocking, it'll go through this complaint process, and there would be a referral for a potential investigation by the Office of the Inspector General.

The Office of the Inspector General would go through that investigation process and make a determination. There are monetary penalties that could be applied for health information exchanges, networks, and developers. There's also penalties under the certification program, obviously. If you are found to be an information blocker, you would not be meeting the conditions of certification, so there are actions that ONC can take there. Then, for health-care providers, the action would be that there would be, quote/unquote, "appropriate" disincentives determined by the secretary. That's an ongoing process right now that HHS is engaged in in determining exactly what those would be. That process would start with a complaint. For right now, the website, again, healthit.gov/healthit-feedback, is the site that you can go to learn a little bit more and engage. Let us know if you have an information-specific complaint at this time.

Pat: Great. Thank you. I guess lastly, to end this, is there any other information that you think might be beneficial to our audience?

Elisabeth: Sure. I do think that there's a couple things going on that are all sort of relevant to each other, and I want to highlight them very briefly. One of the things that's important to understand is what the regulatory process is. Again, this is incredibly wonky, and I apologize to all those who don't think regulations are fun. So that you have a little bit of understanding of the process here, Congress wrote the law. ONC then has put out a proposed regulation. What we are in right now is a public comment period. We've actually extended that public comment period through June 3. So at any point up until June 3, the public, including state agencies, PDMP administrators, other stakeholders that are engaged in this work can submit public comment to us on the proposals in our regulation. We are required, by law, to review each and every one of those. We do, in fact, read each and every one of those and consider that input in making a final rule, which would be the next step.

The next step which would be that we finalize the regulation. Then, at a certain period of time after that, each of the policies that are finalized would become effective. The other thing to take a look at is that CMS also has a proposed rule out at the exact same time, and their comment period is for the same length of time. It goes until June 3. Their proposed rule specifically relates to the interoperability and exchange of information among Medicare and Medicaid payers. So they're looking at CHIP. They're looking at Medicare Advantage organizations and saying that payers, too, should be accountable for exchanging information in an interoperable fashion. So it's something that you might want to take a look at and just see if there's anything in there that might be relevant. I suspect there would be. And to potentially comment on that rule as well.

Then, there's one more thing. I know this is a lot of homework, but there's one more thing that was just recently announced. On April 19, HHS—ONC specifically—but HHS announced a new draft of what we call TEFCA, and it

is, of course, an acronym. It's the government, so everything's an acronym. It stands for Trusted Exchange Framework and Common Agreement. This is another piece of the Cures Act that we don't have to implement by regulation, but we are putting out for public comment. The Trusted Exchange Framework governs how health information moves between and among networks. I think this is going to be particularly relevant, again, for people who are thinking about what could a future state look like for PDMPs. What could it look like for PDMP integration, for PDMP interstate connections, especially, and for moving PDMPs in a direction that allows for not just maybe a view only with related states in a certain area, but also allowing for actual data exchange between PDMPs to allow you all to have a more robust set of data—potentially, a better access to information for longitudinal care records, and potentially easier interstate chairing.

It's just something to keep in mind and take a look at for that future state consideration. The Trusted Exchange Framework and Common Agreement are about network-to-network exchange, ensuring the governance of information to try and free up some of the things that are current business practices or policies that may not be legislated by any law but have been adopted as sort of standard policies that might be causing barriers to exchange, either between networks, between providers who might be on a different network, between providers and entities like public health information exchanges that might be on a different network or in a different setting or in a different state. So it's really trying to address some of those challenges. I would strongly assign that homework piece, as well, to take a look at that and give us public comment on it, especially in consideration of some of the policies in the rule. These things sort of all work together to try and open up the channels by which we're sharing information so that all those of us who are engaged in different parts of this space can actually get to what we really want to be doing, which is improving the outcomes for patients.

Pat: Great. A lot of wonderful information, Elisabeth. Thank you very much for sharing your time and your expertise. I'm sure the information you provided is of great value for the PDMP community.

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