

Centers for Medicare and Medicaid Services
Safety Net Providers
Open Door Forum
Moderator: Jill Darling
Wednesday, June 13, 2018
2:00 p.m. ET

Operator: Good afternoon. My name is (Tiffany) and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Safety Net Providers Open Door Forum.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you.

Jill Darling, you may begin your conference.

Jill Darling: Thanks, (Tiffany). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications and welcome to today's Safety Net Providers Open Door Forum.

Before I hand the call off, just one brief announcement. This open door forum is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in, but please refrain from asking questions during the Q&A portion of the call. If you have any inquiries, please contact CMS at press@cms.hhs.gov. And I'll hand the call off to Rita Vandivort-Warren.

Rita Vandivort-Warren: Thank you. This is Rita Vandivort-Warren who sits over here at HRSA and I want to welcome everyone. We're very pleased. We think we

have a very interesting agenda today but we're always open for new ideas. So, feel free to send those to us.

With that, I'd like to introduce my partner from CMS, Corinne Axelrod.

Corinne Axelrod: Thank you, Rita. Hi, this is Corinne. I'm in the Center for Medicare. And we just have two topics today, but they're both we think very significant and very timely. And the first topic is on the CMS rural health strategy. And we know that not all of you on this call are in rural areas, but we think that it's still of a lot of interest to people and it's a document long in the making.

And I also want to just thank our speaker in advance, Michelle Oswald, for pinch hitting. John Hammarlund was scheduled to do this and John Hammarlund and Cara James, who's the head of the Office of Minority Health, were the leads on developing the rural health strategy. And at the last minute, John, who's a regional health administrator, had -- was called off to do something else.

So, Michelle, thank you so much for filling in on this. And Michelle is very familiar with this report and has been part of the whole process. So, we're in good hands. So, Michelle, do you want to tell us about it?

Michelle Oswald: Sure. Thanks, Corinne. Hi, everyone. My name is Michelle Oswald. And as Corinne mentioned, I work in the CMS Office of Minority Health and I am here representing John Hammarlund and Cara James, who are the co-chairs of the CMS Rural Health Council.

So, as Corinne mentioned, we CMS released a rural health strategy last month. The purpose of the strategy is to inform our work as it relates to rural health and to help CMS achieve its vision for equitable rural health and health care.

The strategy applies a rural lens to our new and our ongoing efforts of the agency and informs our pathway by which CMS can achieve its rural health vision through intra-agency collaboration, through stakeholder engagement

and in elevating our programs and policies to advance the state of rural health care in America.

We all know that rural Americans face many health-related challenges. Rural populations are more likely than urban populations to be living in poverty, to have more chronic diseases. They tend to be older, uninsured or underinsured and medically underserved.

So, understanding this, CMS (sought) to develop a strategy to help make health care in rural America accessible, affordable and accountable. Through a series of listening sessions with rural stakeholders and consumers, the CMS Rural Health Council sought input on challenges and local solutions associated with providing high quality health care in rural communities.

This input informed the development of a strategic plan to improve health care in rural America. The strategy supports CMS' overall effort to reduce provider burden, which you've heard about, I'm sure, and aligns with other existing CMS priorities such as patients over paperwork and addressing the opioid epidemic.

Through the implementation of the CMS rural health strategy and continued stakeholder engagement, we will work to avoid unintended negative impacts of CMS policies and programs on rural communities.

As new rules, regulations and programs are developed, CMS will ensure that the goals of the rural health strategy are considered. As part of the rulemaking process, we also encourage you to participate in the open comment period when stakeholders are invited to submit their feedback and ideas regarding CMS rules, particularly as it relates to health care in rural communities.

You have a link to the rural health strategy in your agenda and the appointment but you can also find the strategy, as well as other rural health resources on our website, which is go.cms.gov/ruralhealth. I'll repeat that again. [Go.cms.gov/ruralhealth](https://go.cms.gov/ruralhealth). You can also e-mail us in our rural health mailbox and that is Rural Health, r-u-r-a-l-h-e-a-l-t-h@cms.hhs.gov. Again, ruralhealth@cms.hhs.gov.

Thank you very much and we look forward to hearing from you and strengthening our partnerships with you to support health care in rural America. And I'll turn it back over to Rita.

Rita Vandivort-Warren: Thank you, Michelle. Very informative. I'm very pleased to introduce Mitchell Berger who is an expert from SAMHSA who can enlighten us about the confidentiality rules as they pertain to (substitutes of disorder) patient records.

As you know, in the last few years, health centers, rural health clinics and other safety net providers have increasingly become engaged on providing substance use disorder treatment. So, it's very important that we understand these confidentiality rules that are different from the HIPAA rules.

So, with that, I'll turn it over to Mitchell Berger to enlighten us more about what we should do and not do.

Mitchell Berger: OK. Thank you, Rita. As Rita said, my name is Mitchell Berger and I work for the Substance Abuse and Mental Health Services Administration. Our agency helps to oversee the confidentiality of substance use disorder patient records regulations, also known as 42 CFR Part Two.

And to give you a little bit of background, the reason we have these separate regulations on confidentiality of substance use disorder patient records is that in the 1970s, Congress enacted statutes intended to protect the privacy of patients that were seeking substance use disorder diagnosis and treatment.

And Congress noted at that time that there was a lot of discrimination associated with people seeking help for substance use disorders and people sometimes were afraid and deterred from entering treatment because of the possibility they could face discrimination and even legal consequences.

So, the current statute, title 42, section 290dd-2 of the U.S. code, among other things, instructs HHS to issue regulations. And those regulations are at 42 CFR Part Two. The statute basically provides that subject to certain

exceptions and exclusions, records of the identity, diagnosis, prognosis or treatment of any patient maintaining connection with the performance of any program or activity conducted, regulated or directly or indirectly assisted by any department or agency of the United States shall be confidential.

Now, the statute also does provide that the patient can disclose information in many cases with prior written consent and it enumerates certain specific exceptions and exclusions. So, as required, HHS issued regulations that are now codified at title 42 in the Code of Federal Regulations Part Two and hence that's why we call it the part two regulations.

Under part two, a federally-assisted substance use disorder program may only release patient-identifying information with the individual's prior written consent, pursue it to a court order or subject to a (few limited) exceptions.

These regulations were initially issued in 1975 and have been substantively updated in 1987, 2017 and most recently in 2018. And our 2017, 2018 updates reflect SAMHSA's commitment to ensuring people receive integrated and coordinated care while at the same time empowering people to govern how their personal information gets shared within the treatment process.

Now, to understand who's covered by part two. It's important to understand; what is a part two program. First, an entity has to be federally assisted. And looking at the statute, the definition of federal assistance in the regulation is fairly broad.

It includes, for example, participating providers in the Medicare or Medicaid programs, being authorized to conduct maintenance treatment or withdrawal management, having tax exempt status or receiving tax exempt donations, being registered to dispense (substance) under the Controlled Substances Act or being supported by funds provided by any department or agency of the United States.

Now, in a program that's federally assisted, you next have to look at the definition in the regulations of program. And first, you would look at does an individual provider provide substance use disorder diagnosis prevention or

treatment, hold themselves out in providing and provide diagnosis treatment or referral treatment.

Now, if you're part of a general medical facility, such as a federally qualified health center, a hospital or a trauma center, you would also look at is there an identified unit within the general medical facility that holds itself out as providing and provides substance use disorder diagnosis, treatment or referral or is their primary function to perform those activities -- to perform those activities?

And how you hold yourself out -- what you can hold yourself out by being authorized by the state or federal government, for instance, being licensed, certified or registered to provide substance use disorder diagnosis, treatment or referral, by the way you notify others such as having advertisements or notices about those -- about performing those activities or by having consultation activities with patients or providers about those issues.

Primary function, for that prong, if you're looking at, OK, what is your primary function, that would suggest that the providers spend a considerable amount of their time on those activities.

Now, it's important to know in the 2017 final rule, while we state that whether somebody's a part two program is in some -- many cases fact specific, we do say that just because somebody has a buprenorphine waiver, for example, does not mean that they are a part two program.

And likewise, simply by virtue of conducting SBIRT, screening, brief intervention and referrals for treatment that does not by itself make somebody a part two program. You have to look at the entire definition of program and federal assistance and -- federal assistance and the regulation.

So, one -- a couple things we did recently is we worked with the Office of the National Coordinator for Health Information Technology, which also has a lot of interest, particularly in terms of electronic health records. And we developed two fact sheets. And these materials now, these fact sheets are

posted along with other materials on the -- on our part two website, which I believe was shared in the agenda.

One of these fact sheets is titled "Disclosure Substance Use Disorder Patient Records, Does Part Two Apply to Me?" And this discusses in a little more detail with some examples and scenarios of the definition of program and how that might apply, particularly in the -- in terms of exchange of information.

The second fact sheet is titled "Disclosure Substance Use Disorder Patient Records, How do I Exchange Part Two Data?" And this fact sheet is focused on how programs such as health information exchanges might function in a part two environment.

And both of these fact sheets, like I said, have examples and scenarios, have illustrations and summarize in a couple pages what can be a fairly complex issue. So, we would definitely encourage you to take a look at those fact sheets.

One other thing I would mention is that we also -- and also included on our part two website is that we held a public meeting on January 31st, which -- of this year, which we were required to do by the 21st Century Cures Act, to get input from the public about this part two impact patient care, health outcomes and patient privacy. And we had about 1,200 people participating either online or in person.

And we got a number of comments from that meeting and you -- if you go to our part two website, you can see the materials, the -- a summary of the comments we received, a transcript of the listening session and other resources.

So, we are aware, definitely of -- and have got a lot of comments about issues such as electronic health records, consent, aligning part two with HIPAA and other issues and certainly -- we're certainly aware of those issues and we hope to continue to provide (sub-regulatory) guidance like these fact sheets and to work with our partners at HRSA and elsewhere to -- ONC and elsewhere to effectively implement part two.

So, with that said, Rita, I'll turn it back over to you for any questions.

Rita Vandivort-Warren: OK, thank you. Jill, would you like to manage our question-and-answer period?

Jill Darling: Thanks, Rita. I'll just hand it back to (Tiffany), our operator, to open the lines, please.

Rita Vandivort-Warren: OK, thank you.

Operator: As a reminder, ladies and gentlemen, if you would like to ask a question, please press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. Please limit your questions to one question and one follow-up to allow other participants time for questions. If you require any further follow-up, you may press star one again to rejoin the queue. We will pause for just a moment to compile the Q&A roster.

Your first question comes from the line of (Michelle Sonner) with (Healthcare Partners). Your line is open.

(Michelle Sonner): Hi, good afternoon. This is (Michelle Sonner) from South Carolina. I did not receive an agenda. Where would I find that at? Can you hear me? Can you hear me?

Rita Vandivort-Warren: Yes. If you actually go to the CMS website, cms.gov, and put in the search box open door forum, you'll get a long list of open door forums. And look down to the safety net provider one and you will open that up and you'll see this agenda with links that have been discussed today. Now, Jill, you may do a better job of something I missed.

Jill Darling: You really can go to any open door forum web page, even just Google open door forum CMS and there's a link to sign up. And you can enter in your e-mail and check off which of the open door forums you'd like you receive information from.

(Michelle Sonner): OK, and then my second question is...

Rita Vandivort-Warren: Yes...

(Michelle Sonner): Can I...

Rita Vandivort-Warren: Go ahead. I would -- this is Rita. I was just going to say the name of this one if you're not familiar with it is the safety net providers' open door forum, so...

(Michelle Sonner): Right, yes, ma'am. I signed up for it through the HRSA e-mail.

My second question is related to the (AMES) grant and, you know, the primary function. It's my understanding that if your primary function is not mental health but you're just accommodating the (AMES) grant and, you know, you have written in your services specific to the (AMES) grant, that that is not considered your primary service and therefore you may not be CFR Part Two eligible. Is that correct?

Corinne Axelrod: Mitchell, is that something that you can address?

Mitchell Berger: I'm not really prepared to answer that question because I don't work on the (AMES) program. What I -- all I can really do is reiterate that its facts specific and you would have to take a look at the definition of program. I couldn't comment categorically whether somebody getting a particular grant is or is not a part two program.

(Michelle Sommer): Got you.

Operator: There are no further questions in queue at this time.

Corinne Axelrod: Well, this is Corinne again. And I would like to just thank everybody and encourage you to let us know if you have any agenda items that you'd like us to discuss. We're always happy to hear from you and gather the experts on whatever topic is of interest. So, please let us know. You can e-mail either Rita or you can e-mail me or Jill and we'll do what we can to get people on the calls who can provide information that will be hopefully useful to you. Jill?

Jill Darling: Well, thank you, everyone. Have a great day. And you get some of your day back. Thank you.

Rita Vandivort-Warren: Thank you.

Operator: Thank you for participating in today's Safety Net Providers Open Door Forum Conference Call. This call will be available for replay beginning at 5 p.m. today, June 13th, 2018 until 11:59 p.m. Eastern time June 15th, 2018. The conference I.D. number for the replay is 33261942. The number to dial for the replay is 855-859-2056. This concludes today's conference call. You may now disconnect.

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