Perspectives from the Field Interview Series

Interview with Eric Goplerud, PhD

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Interviewer: Jane Hyatt Thorpe
Questions:
1) Please introduce yourself and tell us about your current position.
2) How does what you do intersect with health information exchange?
3) Briefly, what are the Part 2 regulations that govern substance abuse information in medical records, who do they apply to, and how do they relate to health information exchange?
4) How do new technologies such as EHRs help or hinder the sharing of patient substance abuse information?
5) Should the Part 2 substance abuse regulations be modified to address the role of new technologies that enable greater exchange of substance abuse information and new integrated models of care delivery?
6) What is your sense of SAMHSA's willingness to modify the Part 2 substance abuse regulations to achieve a better balance?
7) Whether or not the Part 2 regulations are modified, what are the best pathways to share Part 2 patient substance abuse information with care team providers and other related social services?
Transcript:

Question 1

JHT: Welcome to the Health Information and the Law Perspectives from the Field Interview Series. Today we are speaking with Eric Goplerud, Senior Vice President and Director of Substance Abuse, Mental Health, and Criminal Justice Studies at NORC at the University of Chicago.

Welcome, Eric. Thank you so much for joining us today. Would you please tell us a little bit about your current position and how it intersects with health information exchange?

EG: Sure. I am a Senior Vice President at NORC at the University of Chicago. I direct a Department of Public Health here at NORC with responsibilities that include substance use, mental health, as well as public health research and data analysis. For more than a dozen years, I've been working to integrate substance use into good health care and substance use into health. There are a number of very important developments that have been making that more possible. The Mental Health and Addictions Parity Act in 2008, the Affordable Care Act, the coverage of preexisting conditions under the Affordable Care Act, the expansion of Medicaid programs and the health exchanges to cover more people who have mental illness and substance use disorders, now covered by insurance who in the past would only have been covered by government sources and by grants; and leading research and learning collaboratives on screening and brief intervention for risky alcohol and drug use and treatment that takes place within the health care setting. So, as we are moving health care to care for the entire person, where we have insurance coverage that is covering the entire person, not excluding conditions such as substance use disorders and mental illness, health information exchange becomes absolutely critical for quality care, safe care, and efficient and valuable care, or as CMS is talking about the triple aims, at getting high value for resources expended. And the integration of people with substance use disorders, or people who have co-morbid substance use conditions with other medical conditions, into good health care, has got to be complemented by integration of data about their health utilization, about their treatment, into the electronic health records.

Question 2

JHT: Wonderful. Thank you so much. I think you referenced the role of substance abuse information in medical records and the importance of including that information in medical records, as well as we move towards a more integrated health system. There has been discussion around the Part 2 regulations that govern substance abuse information, in medical records in particular. I'm hoping you can briefly describe who they apply to and how they also relate to the exchange of health information.

EG: The federal substance use privacy regulation, often referred to by the federal regulatory nomenclature of "42 C.F.R. Part 2," covers all substance use treatment information in substance use treatment programs. Substance use treatment programs are defined by the law and by regulation as any program that holds itself out to be treating or diagnosing substance use conditions (that's alcohol, drugs, misuse of prescription drugs), a program that holds itself out and that also receives any federal funding is considered a "Part 2 program," a program whose health records all fall under the purview of the federal substance use privacy regulation. The conditions of the exchange of health information in Part 2 organizations are very tightly constrained.

42 CFR Part 2 gives substantial control over the exchange of the covered record to the patient. The patient must specifically give permission for the exchange of any information from a Part 2 covered organization with any other organization and puts very strong controls on the release of the information without the explicit consent of the patient with a named organization or individual to receive the information, a description of the type of information that can be exchanged, and the length of time for that permission for the exchange of information is valid. It also prohibits re-disclosure of that information by the receiving individual or organization, and that receiving organization is required to maintain those same confidentiality and privacy controls over that information. This clearly creates difficulties in an environment of electronic health records and health information exchange, where there are extreme difficulties of identifying specific individuals by name who would be receiving information and the opportunities and the networking of re-disclosure that takes place within a health information exchange makes the exchange of 42 CFR [Part 2] covered information extremely difficult. Difficult to the level that most health information exchanges simply do not include 42 CFR [Part 2] covered information within their HIE. The consequence of this is that patients who are receiving substance use treatment in a Part 2-covered substance use treatment program are likely to not have their health information entered into a health information exchange or into the exchange of health records. This is only for those specific specialized substance use treatment programs that hold themselves out under the regulatory regime as providing substance use treatment services and that receive federal funds. There are large numbers of patients who are screened, identified as having a substance use disorder, and who are treated within primary health care, hospital emergency departments, hospital inpatient settings, and other health care delivery settings. If they are identified, diagnosed, and treated within those settings, their information is protected by HIPAA only, not the 42 CFR [Part 2] regulations. As we are moving more and more health care into integrated health care systems, we have this very peculiar situation where a patient who is diagnosed and treated for alcohol dependence or drug dependence in a community health center, their information may be relatively freely exchanged within a health information exchange or health system. A patient who receives the same diagnosis and the same treatment in a substance use treatment program is likely to not have that information exchanged at all within a health care system. So, depending on the place, the physical location and the license, information may not be exchanged; care quality, efficiency, safety, may or not be compromised by the absence of information about a patient's health status.

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Question 3

JHT: That's very interesting. So it sounds like it's a location-specific issue depending upon who the Part 2 regulations apply to. Which leads us into our next question related to new health information technologies. There has been greater use of electronic health records across the care continuum by a number of different providers. How are you seeing those new technologies that allow greater electronic exchange of health information either helping or hindering the sharing of substance abuse information, either in a Part 2-regulated setting or an external setting?

EG: The growing capability of our health information systems to exchange information between providers efficiently and safely is driving the Substance Abuse and Mental Health Services Administration (SAMHSA) to reconsider the current regulations of 42 CFR [Part 2]. It is the rapid expansion since ARRA and ACA of electronic health records and the increasing recognition of how valuable it is to exchange information in order to improve the quality, safety, and efficiency of care that is driving SAMHSA and the federal government to reexamine the current regulations. But as we're looking at technology, I think it's helpful to kind of step back and think about what it is we're trying to accomplish. In the Hippocratic Oath, there is a confidentiality pledge. That pledge says, "All that may come to my knowledge in the exercise of my profession or in daily commerce with men which ought not to be spread abroad, I will keep secret and will never reveal." Now this is a general pledge; it is not specific to addiction or the treatment of addiction. But the most revered portion of the Hippocratic Oath is, "I will prescribe regimens for the good of my patients, according to my ability and my judgment, and never do harm to anyone." That would lead a physician or health care provider to exchange information for patient safety and good patient care. The aim would not be to dismantle the Hippocratic Oath for people who have a substance use disorder, but to demonstrate how health teams and health homes, with information being freely shared among health teams, promotes patient care. Pointing out that there are many ways that electronic health information systems can be hacked, where information may be inadvertently disclosed, does not in itself create a reason that substance use records should be kept out of electronic health records or HIEs. The substance use privacy law was set up to protect people who were engaged in illegal behavior. The aim was to help people engaged in illegal activities to feel safe to come into treatment. But we in the substance use treatment field that is protected by 42 CFR Part 2 are doing a terrible job of actually getting people into treatment. About 95% of people who meet the criteria of a substance use disorder did not seek treatment or want treatment. Of the 5% who want treatment but did not get it, 4% did not want to stop using. Currently, we're treating about 2.3 million people in specialty substance use care, perhaps one in ten of the 23 to 25 million persons in America who have a substance use disorder. We're perhaps treating one in ten who need and could benefit from treatment. If 42 CFR [Part 2] was set up to help people get into treatment, then how come it isn't working very well?

Question 4

JHT: Is that one of the critical issues that SAMHSA is working to identify as they think about modifying the Part 2 substance abuse regulations, incorporating the concept of the new technologies that are available and, of course, greater emphasis on the exchanging of health information and new, integrated models of care?

EG: That's exactly one of the three areas that SAMHSA was particularly focusing on in the <u>listening</u> sessions that took place in early June. SAMHSA was quite concerned about how protected information under 42 CFR [Part 2] could be entered into health information exchanges. They were asking specifically about whether it was possible, rather than identifying, on a consent [form] to share records, rather than

identifying a specific physician, nurse, or health care provider, as currently is required under the current regulations, that it may be possible to identify an organization or organizations, or permit disclosure into a health information exchange. They were also interested in exploring the idea of the development or use of a mechanism permitted under 42 CFR Part 2 of a qualified service organization arrangement, essentially a contract between specialty substance use treatment providers and a health care provider or system to provide services for patients with a substance use condition; whether the qualified service organization arrangements could be used for covering a health information exchange and a substance use treatment specialty organization. So, they're very much trying to figure out how to accommodate the requirements which are very strict in law and regulation, how to protect the privacy of patients who may be engaging in illegal behavior, or whose behavior, if exposed inadvertently without their permission, could lead to discriminatory outcomes (worse health care outcomes or could be used for discrimination in other forms of insurance, housing, employment) - how to protect that sensitive information from being disclosed in a way that could harm them or could prevent individuals from disclosing that they have a treatable substance use condition. They're really caught in a very difficult position because there are very good reasons to believe that. It's a highly stigmatized condition, and health care providers often share the public prejudice against people with addictions, and consequently treat people with addictions with less empathy and less care. In fact, we've seen instances of physicians essentially firing their patients, saying they cannot treat them knowing that they have an addiction. On the other hand, we have had many, many instances of patients being medically harmed because information about their substance use condition is not available to their treating health care provider. I got a call a couple of months ago from a physician in Minnesota who was at the same time furious and really sad because he had a patient who was on methadone, which he did not know and the patient didn't disclose, who came in and asked for medications to treat anxiety. He gave the patient benzodiazepine and the patient died of respiratory arrest, a preventable medical crisis, and he wanted to know what could we do to change this, how could similar kinds of deaths be prevented. Five medical societies whose responsibilities include treatment of addictions (the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, and others) wrote a letter to SAMHSA and the Office of the National Coordinator for Health Information [Technology] a couple of years ago strongly recommending that for patient safety, quality, and efficiency, a very minimal amount of information be disclosed into health information exchanges: diagnosis, medication treatment, and dates of treatment, and that's it. But they recommended that that information was essential for patient safety, quality of care, and for continuity of care, and I think it's really important to listen to the health provider leadership recommending that for patient safety, quality, and care, that some minimal information can and should be included in the health record.

JHT: Before we move on to our next question, I just want to clarify for our listening audience that we've been referring to SAMHSA, the Substance Abuse and Mental Health Services Administration, which is an agency under the Department of Health and Human Services.

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Question 5

JHT: So Eric, following up on your last response, talking about the letter and encouragement from the professional societies that is coming to SAMHSA in particular, and given the town hall that was held earlier in June, what is your sense of SAMHSA's willingness to seriously consider modifying the Part 2 substance abuse regulations to achieve the better balance, in terms of integration of quality and safety of care, that we've been talking about?

EG: I think the likelihood is very great. The Director of the Center for Substance Use Treatment, Dr. Westley Clark (the Center for Substance Use Treatment is one of the three centers within SAMHSA), told me that SAMHSA anticipates putting out a Notice of Proposed Rulemaking, essentially a modification of 42 CFR [Part 2], sometime this summer and is likely to be putting out a final rule before the end of the year. It is hard to forecast exactly what changes will be included. Clearly, there will be a period of public comment and information gathering that will take place between the time of the notice and the time the final rule is published, but I suspect it will relate to the ability of a patient to give permission to an organization or to an HIE (rather than to specific individuals), will allow for an indefinite length of time that records can be shared, will permit the re-disclosure of information (perhaps under conditions similar to HIPAA, for the purposes of treatment, payment, or administration). What we have also advocated is that as we're moving substance use into good medical care, that we look to how we can increase the protections on sensitive information. The Genetic Information Nondisclosure Act, or GINA, says that information about a patient's genetic information can be shared for the purposes of treatment without the patient's express permission, but it's not permissible for that information to be used for insurance, housing, education discrimination. I think that GINA actually doesn't go far enough for people with addiction or other sensitive conditions. Inadvertent or advertent disclosure of information ought to be protected so that it cannot be used in civil or criminal procedure. If that information is disclosed, it should be considered legally tainted and cannot be used.

JHT: Well, it's very exciting to hear that there will be activity coming out of SAMHSA and I'll just mention for our listening audience as well that we'll post a summary of the town hall that Eric mentioned and other related materials alongside this interview so we hope that people will access those as well.

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Question 6

JHT: Eric, one final question for you. Whether or not the Part 2 regulations related to substance abuse are modified, any thoughts on currently best pathways to exchange information that may include patient substance use information with care providers?

EG: I think there are three things health care teams and providers can do. First and foremost, it's really important to be consulting with a health information lawyer, which I am not and I cannot give legal opinions. It's very important in this area that you talk to a health lawyer. Second, this method that 42

FG: Thank youl Good bye

CFR [Part 2] permits of a qualified service organization agreement has been used and is being used between substance use treatment programs and community health centers or between substance use treatment programs and hospitals or other health care systems, where essentially what is being done is a contractual arrangement to provide information back and forth about shared patients. This works well for specific substance use programs working with an ACO or with an HIE. So, the qualified service organization agreements may be one vehicle for permitting the flow of information. And then the third and probably the most promising, which doesn't require any changes to 42 CFR [Part 2], is to bring the substance use care (the identification, diagnosis, early intervention, and treatment) inside the health care team and inside the administrative organization of the health care system. If what we are finally recognizing is that the head is connected to the rest of the body; that addiction is a significant comorbidity that is associated with unstable hospital discharges, higher medical costs for diabetes, hypertension, and other conditions, and is itself a risk factor for a wide range of injuries and illnesses; as we are increasingly recognizing that the head and the rest of the body are connected, it makes sense that as part of a patient-centered medical home, ACO, HIE, or health umbrella organization, that substance use care should be brought inside, not as a separate freestanding substance use treatment entity, but as part of good medical care. The same thing is being done with mental health care, STDs, and smoking and tobacco use. We cannot improve the quality of care, we can't get consistent and better outcomes and value for resources expended, if we do not bring substance use, mental health, and health together into a health home for our patients. And that really is, I think, the direction that the health care system is taking, and which increasingly is going to make 42 CFR Part 2 irrelevant, because the health care system is going to be recognizing and incorporating substance use treatment as a routine part of good primary care and also good acute medical care in hospitals and EDs.

JHT: Wonderful. Eric, thank you so much. This has been incredibly helpful and informative, and we greatly appreciate your time. So thank you very much!

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Further Resources:

- SAMHSA:
 - http://www.samhsa.gov/
- Summary of Part 2:
 - http://www.healthinfolaw.org/federal-law/42-cfr-part-2
- SAMHSA FAQs on Applying Part 2 to HIE:
 - http://www.samhsa.gov/healthprivacy/docs/ehr-faqs.pdf
- Recording of SAMHSA Listening Session on Part 2, June 11, 2014
 - https://www.youtube.com/playlist?list=PLBXgZMI_zqfTRftyiS4ckNi9bYW4Vmj82
- Center for Substance Use Treatment:
 - http://beta.samhsa.gov/about-us/who-we-are/offices-centers/csat
- Summary of HIPAA:
 - http://www.healthinfolaw.org/federal-law/HIPAA