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Committee on Energy and Commerce, Subcommittee on Health
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Re: Confidentiality of Substance Use Disorder Patient Records, Combatting the Opioid Crisis, Prevention and Public Health Solutions

We appreciate the opportunity to provide input to the Committee on Energy and Commerce, Subcommittee on Health. **It is our position that Part 2's heightened protections for substance use disorder records promote patient care, health outcomes and privacy, and that it is vitally important to maintain patient confidentiality in order to ensure that people enter treatment for substance use disorders.**

I am a licensed psychologist and have worked across three states treating substance use disorder (SUD) in a range of settings including outpatient, intensive outpatient, residential, hospital and prison settings. Further, I have worked with clients who can afford to pay by cash for fear of disclosure of their private information, as well as those who cannot afford treatment unless it is funded by government agencies. In these 25 years of experience in the field, there are some consistent concerns as I will outline below.

I am writing representing Gaudenzia Inc, a non-profit treatment provider specializing in SUD, with programs spanning outpatient, intensive outpatient, and residential treatment programs. Celebrating 50 years in operation, Gaudenzia operates 151 programs at 82 facilities throughout Pennsylvania, Delaware, Maryland and Washington, DC. System-wide last year, 17,087 individuals were admitted into treatment. Over 1,000 Gaudenzia staff reflect the diverse treatment population with numerous employees at all levels who have many years of experience in recovery, understanding the role of treatment, recovery and privacy protections.

Any discussion of proposed changes must first begin with the context of why these protections exist. The stated purpose remains: "They are intended to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment." 2.2(b)(2) There are a number of these adverse impacts which one is vulnerable to ranging from housing, life insurance coverage, loans, employment, licensure and a range of related discrimination that may be intentional or merely passive.

Put simply some of the importance of privacy protections include the following risks:

- Once labeled, it can affect clinical decision-making for a lifetime.
- Some violations that cannot be amended, such as prison time, loss of employment etc.
- Serious losses/damage in people's lives, employment and relationships.
- Individuals not seeking treatment/delaying onset of treatment.
- Individuals not sharing key information regarding guilt/shame/trauma for fear of disclosure.
- Professionals such as teachers, physicians, government workers and others may avoid treatment for fear of harm, causing the SUD to progress into greater severity before being treated.
- Damage to treatment leads to increased rates of SUD and associated societal impacts (overdose, crime, child welfare, health conditions).
- Denial of proper medical care (e.g. refusal of pain medication, even in cases of acute trauma or end-stage cancer).

The protections of 42CFR Part 2 highlight similarities and differences with HIPPA. While we have made great strides in understanding that SUD is a disease, not a moral failing, this does not mean that every disease is treated the same. Simply stated, SUD is unique in a number of ways. For example, you do are not incarcerated for having a heart attack, you are not fired for having cancer, and you are not denied visitation to your children due to severe acne. Disclosure of SUD has tangible vulnerabilities that are not the same as other medical conditions.

In order to understand the impact, it is important to consider any further changes from the perspective of the individuals with SUD, from the SUD counselors who treat them, as well as the historical and current landscape:

- **It is critical to understand the issue of confidentiality protections from the perspective of those with a substance use disorder, who are often afraid of harms associated with disclosure of their personal information.** Remember that many of these individuals in active addiction do not have a voice because they are not even aware of this debate over their protection of confidentiality, happening thousands of miles away.

Their lack of voice may not be an indication that they are not concerned about confidentiality protections. The National Survey on Drug Use and Health continues to survey thousands, showing that shame and fear of retribution remain key reasons why people avoid treatment, afraid of the impacts on employment and judgement in the eyes of their neighbors and friends. Their focus should be on their treatment and establishment of recovery not on politics aimed at protecting their right to privacy, Appendix A contains a list of examples of the intensity of judgement of faced directly and indirectly by those with SUD. Appendix B contains a list of examples of harms associated with disclosures of private information. These harms and discrimination are difficult to identify or prosecute. Worse, inappropriate disclosures are virtually impossible to remedy since there is no way to "undisclose" what has been shared. A most egregious case example is that of individuals being denied life insurance because they have a history of being prescribed naloxone, the overdose reversal medication. Remember that the one's purchasing naloxone, are often not the person with SUD, but the mothers, brothers and children trying to prepare to save the lives of a loved one.

- **It is important to consider the will of those we are representing.** Often discussions of confidentiality are centered around the inconvenience of obtaining releases or other nuisances to the health care system which is too busy to learn about rules for licensing and confidentiality protections. This focus ignores the individuals who are at risk themselves, who could simply be asked the information directly. This disrespect suggests an underlying stigma that we know better than the patient, or worse an outright contempt for "those people" who are simply scamming for medication.

- **With the intense emphasis on the opioid epidemic, it is important to remember that most individuals with SUD do not use opioids.** Data from the National Survey on Drug Use and Health reveals that 65 million Americans 12 and Older admit to binge drinking in the past month. Of these, 16 million admit to being heavy drinkers. We should also be aware that 24 million people admit to being past month users of marijuana. These numbers alone suggest the magnitude of the issues we are confronting today, as they exceed the 3.4 million people who admit to past month use of pain relievers and the 475,000 who admit to past month users of heroin. This highlights the broad range of individuals affected, most of whom are in the workforce, including doctors, lawyers, teachers and others.

- **In the context of an opioid epidemic, it is important to consider the effect that any changes have on the treatment process which is predicated on the establishment of a safe environment where individuals with SUD can explore the causes and solutions to their disease.** Treatment occurs in the context of a supportive relationship, where individuals feel safe to explore their deepest underlying fears, beliefs and judgments that trigger escape into substance use. Confidentiality is the key element in creating the safe relationship where recovery can take root and grow. Every time the confidentiality protections are changed, every clinician needs to learn about it, consult with lawyers to

determine the application of the changes, develop new informed consents/policies/procedures, and train counseling and supportive staff on the changes. Perhaps worst of all, we must then go to each client and inform them of the change, along with the new agreement of what will or will not be protected. This is incredibly damaging to the treatment relationship and trust that is necessary for an individual to share his/her most vulnerable information. Clinical records may contain very personal quotes regarding a person's fear, shame, or victimization that should only be shared by the individual, when they are ready, and in the context of trusting relationship, rather than through broad dissemination of this information without context. Engagement with a positive therapeutic alliance is critical to successful outcomes. This includes a patient's trust that they may remain in control of their most sensitive information. While some may choose to disclose personal information, that must remain their choice so that these decisions are not made without those whose information is at risk.

- **Historical perspectives should be remembered, so we do not repeat the mistakes of the past, since the stigma and adverse impacts of disclosures are as much a concern today (if not more) as they were in the days of the original implementation of 42CFR Part 2.** The original confidentiality protections were established at a time when there was rampant opioid use, as well as risks of prosecution for those who were using drugs. Appendix C includes examples of the types of rulings and discussions from the day. Courts and congress through the decades have reiterated the central role of privacy in the treatment relationship. In one example they indicate that this is even more sensitive than the relationship with a physician, instead comparing the nature of the counseling relationship to that of priest/penitent. Today, individuals with SUD continue to face the risk of discrimination, loss of employment, loss of their children, and criminal charges for the behaviors associated with their disease.

- **The current landscape includes regular public discourse on the risks of "hacking", "leaks", "ransomware", and outright data breaches of public and medical information, making digital sharing of private information more risky, in a way that was not possible years ago.** Years ago, inappropriate disclosures would only share the protected information to a limited number of individuals. Today, when personal records can be merely data to be bought and sold, inappropriate disclosures can expose one's history to thousands. This can lead to widespread harm that is very difficult to undo. Appendix D outlines some recent data breach materials. Additionally, every electronic health record (EHR) is different, which creates risks of error. Functionally, my EHR would upload to a regional EHR hub, which would then connect to a state or national level EHR, before it would then be shared down to another regional EHR and ultimately to another program, which could have yet another EHR system. This complexity creates

risks of error in data sharing that could result in misinformation about an individual, leading to improper treatment decisions.

With regard to Part 2's effect on patient care, health outcomes, and patient privacy, Gaudenzia supports the following principles:

- **Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago in order to protect patient care, health outcomes, and patient privacy.** If patients are afraid that their treatment records will be used to criminally investigate or prosecute them, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, they will not enter treatment in the first place. Part 2 prevents patient records from being used against them in such proceedings without an individualized inquiry into the relevance of the patient records and the potential harm to the patient upon disclosure, whereas HIPAA's lower privacy standard provides no such protections. In the midst of a national emergency and growing rates of fatal drug overdoses, Part 2 provides a crucial guarantee to the millions of people in treatment and the many millions more with an unmet need for treatment, that it is safe to enter treatment.

- **Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.** This includes disclosures to the general health care system, health information exchanges ("HIEs"), health homes, accountable care organizations, and coordinated care organizations. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure. In addition, we worry that some individuals may not fully understand the implications of giving this information while in withdrawal or frightened.

- **Electronic Health Record ("EHR") systems must accommodate heightened protections for health information – not the other way around.** It is both necessary and technologically possible to integrate substance use disorder information and maintain patient confidentiality. Moreover, Part 2's heightened privacy protections are just one of many heightened privacy protections in state and federal law for sensitive health information – including state laws protecting mental health, HIV status, reproductive health, and domestic violence history – and eliminating Part 2 will not absolve EHR systems from addressing the need to meaningfully segment health information data.

- **It is damaging to initiate additional changes to Part 2.** SAMHSA has recently reviewed feedback from hundreds of entities and updated Part 2. New amendments made to Part 2 by SAMHSA in 2017 and 2018 have made it even easier to allow (with patient

consent) for the sharing of health information between Part 2 programs and other health care providers. Many vendors, health care providers, and substance use disorder treatment programs do not understand these new amendments and how to utilize Part 2 as effectively as possible. Every time there are changes, it impacts treatment providers who need to develop new training. Every change also erodes the trust of those with addiction making them less likely to access treatment and remain in treatment.

In light of these principles, we recommend the following:

- Refrain from further changes to 42 CFR Part 2.
- Strengthen the enforcement of sanctions on those who disclose or re-disclose protected information.
- Fund infrastructure for development of information technology systems that can safely handle this information with appropriate permissions for different users, and inter-program communication to prevent inadvertent data errors in upload/downloads.
- Fund programs to hire data entry processers, train all staff, purchase equipment and upgrade data systems.
- Remember that SAMHSA has already conducted an extensive review and "final" ruling on this matter, and that the continued discussion has a chilling effect on those who are desperately in need of a safe haven to begin their recovery journey.
- Remember that this is not a matter of inconvenience, but rather a critical protection so that individuals feel safe to enter treatment, safe to explore their deepest fears, as they work to establish recovery. Without this protection, treatment fails.

We urge the Subcomittee to consider our comments and think carefully before taking any steps that may further increase the vulnerability of substance use disorder treatment records. Based on the reasons outlined, we oppose additional damaging changes to 42 CFR Part 2 at this time.

Thank you for your careful consideration in this complex issue that is so sensitive in the context of the current epidemic.

Sincerely,

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Appendix A

Examples of Public Stigmatized Attitudes

Consider the rampant depth of stigma from recent blog posts such as:

- "Overdose is nature's way of taking out the trash"
- [re: Naloxone] "Thanks for saving him. Now he can continue to steal to support his habit."
- "Very mixed feelings here. Do I care if some drug user dies? Not really. Do good people make mistakes and deserve a second chance? Yes."
- [Re: Naloxone] "Should make a one per person law. If someone survives because of this miracle drug and they still can't appreciate their life and are stupid enough to use, don't waste the money/time on trying again.
- **"I have plenty of compassion for those who deserve it. I have no compassion for those that made their own problems such as dopers, pedophiles and murderers"**

Recently, the opioid epidemic has increased negative attitudes toward those with SUD due to their repeated returns to the emergency departments, and law enforcement who has responded and revived the same individual repeatedly.

Appendix B

Examples of Adverse Impacts

Stigma leads to subtle and obvious discrimination. Consider the numerous examples cited by the Legal Action Center in their response letter to these proposed changes dated June 25, 2014, and from Faces and Voices of Recovery's response:

- "A young father in recovery who was being denied visitation with his children because he was in methadone treatment, despite the fact that he was not using any illegal substances;"
- "A mother in recovery who had her 2-month-old infant removed from her custody after the hospital where she gave birth reported her for having legally prescribed methadone in her system;"
- "A young mother who was being threatened with eviction from a shelter because she was taking prescribed methadone for her opioid addiction (another young mother had already been evicted from the same facility for the same reason, and had become homeless; neither woman was using illegal substances);" and
- "A young man whose employer refused to allow him to return to work after he successfully completed treatment for alcoholism, saying that he was a safety threat even though his physician had cleared him to return to work with no restrictions."
- "A 29 year old mother who lost her 3 year old in a child custody case because, after the unlawful disclosure of her addiction treatment records, she was deemed unfit by a judge and her child was put in the custody of child protective services.
- "A bright young lawyer who learned after two weeks at her new job that she would be terminated because the fact she was on methadone came up in a background check."
- "A small businesswoman had to give up her dream of owning her own business because she could not get a health insurance policy for her employees;" and
- "A husband with four children who was in a high risk fisheries job was unable to get life insurance to protect his wife and children."

In addition to these personal examples, with the widespread use of naloxone, cases are emerging of adverse impact such as denial of life insurance. To receive this sanction, the only crime these individuals committed is that they love someone with SUD.

Appendix C

Examples of Historical Considerations Still Relevant Today

The discussions that occurred in about confidentiality protections in the 1960's and 1970's are as relevant today as they were then:

- "The psychiatric patient confides more utterly than anyone else in the world. He exposes to the therapist not only what his words directly express; he lays bare his entire self, his dreams, his fantasies, his sins, and his shame. Most patients who undergo psychotherapy know that this is what will be expected of them, and that they cannot get help except on that condition. . . . It would be too much to expect them to do so if they knew that all they say-and all that the psychiatrist learns from what they say-may be revealed to the whole world from a witness stand." (Cited in *Duke Law Journal*, Soffin, 1985)
- "First, communications from a patient to a psychotherapist do originate in the expectation of confidentiality. Psychiatric patients divulge to their therapists secret thoughts and emotions that they would not reveal even to their families or close friends. Communications that are made during therapy may reveal unattractive and antisocial tendencies of the patient; thus psychotherapy patients expect and demand confidentiality in return for their open disclosure. Second, this element of confidentiality is essential to a complete and satisfactory relationship between the parties. In order for treatment to be successful, patients must be able to communicate their thoughts and emotions freely and fully, even when such thoughts are abhorrent to society. **If patients suspect disclosure of their confidences, they will hesitate to consult a psychotherapist and may forego needed treatment.** Emotional and social problems, if untreated, are detrimental to both the individual and society. (Cited in *Duke Law Journal*, Soffin, 1985)
- "Among physicians, the psychiatrist has a special need to maintain confidentiality. His capacity to help his patients is completely dependent upon their willingness and ability to talk freely. This makes it difficult if not impossible for him to function without being able to assure his patients of confidentiality and, indeed, privileged communication...[While] there may be exceptions to this general rule, there is wide agreement that confidentiality is a sine qua non for successful psychiatric treatment. The relationship may well be likened to that of the priest-penitent or the lawyer-client. Psychiatrists not only explore the very depths of their patients' conscious, but their unconscious feelings and attitudes as well. Therapeutic effectiveness necessitates going beyond a patient's awareness and, in order to do this, it must be possible to communicate freely. A threat to secrecy blocks successful treatment. (*Taylor v. US, 1955*)
- "In regard to mental patients, the policy behind such a statute is particularly clear and strong. Many physical ailments might be treated with some degree of effectiveness by a doctor whom the patient did not trust, but a psychiatrist must have his patient's confidence or he cannot help him. "**The psychiatric patient confides more utterly than anyone else in the world. He exposes to the therapist not only what his words directly**

express; he lays bare his entire self, his dreams, his fantasies, his sins, and his shame. Most patients who undergo psychotherapy know that this is what will be expected of them, and that they cannot get help except on that condition…It would be too much to expect them to do so if they knew that all they say — and all that the psychiatrist learns from what they say — may be revealed to the whole world (*Taylor v. US, 1955*)

- "The conferees wish to stress their conviction that the strictest adherence to the provisions of this section is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem to be overcome." (*U.S. Code Congress & Admin. News*, 1972)

Appendix D

Data Breaches in the Modern World

The scope of risk of adverse impact must be considered in light of the context of data security. In February 2015, Anthem, Inc., the largest for-profit managed health care managed health care company in the **Blue Cross and Blue Shield Association, disclosed that criminal hackers had broken into its servers and potentially stolen over 37.5 million records that contained personally identifiable information from its servers.**

Such cyberattacks are on the rise and are now expected to be a constant source of concern throughout the healthcare industry as patient information is shared across various technology platforms. The publication Becker's Hospital Review regularly collects and reports the latest data breaches, often on a monthly basis. The data security of insurance companies, outpatient providers and other entities that work with patient information is variable, posing a never-ending danger that patient information could be compromised and that the outcomes will be troubling for those persons whose healthcare information is obtained in this nefarious manner. **Russell Branzell, president and CEO of the College of Healthcare Information Management, has said that "Healthcare is ground zero for cyberattacks."**

According to the Department of Health and Human Services, while all industries continue to face a growing threat of attacks on their information systems, the size and scope of attacks on health care information systems have accelerated particularly rapidly in the past two years. The Department recently announced the members of its Health Care Industry Cybersecurity Task Force, representing a wide variety of organizations within the health care and public health sector, including hospitals, insurers, patient advocates, security researchers, pharmacy and pharmaceutical companies, medical device manufacturers, health information technology developers and vendors, and laboratories.

More recently, Aetna allegedly disclosed the names of 13,487 Aetna customers who had the medications were taking HIV medications. This has led to a lawsuit seeking over $20 million. Individuals could receive a settlement of merely $75-$500 to compensate them for any harms associated.

Historically, in the context of paper records, confidentiality violations were very limited due to the need to either access the paper record, or have a clinician purposely disclose information. In the age of big data, each data breach can violate millions of affected individuals, exponentially increasing the risk of harm to this vulnerable population.