



Board of Directors

Mark W. Parrino, M.P.A.
President

Janice F. Kauffman, R.N., M.P.H.
First Vice President
Massachusetts

George E. Stavros, M.D.
Second Vice President
Arizona

Michael Rizzi
Treasurer
Rhode Island

Tina Beckley, M.A.
Secretary
Colorado

Board Members

Alabama
Susan Case, M.S.

California
Jason Kletter, Ph.D.

Connecticut
Paul McLaughlin, M.A.

Florida
Gloria Hanania, LMHC

Georgia
Stacey Pearce

Illinois
Kate Mahoney, LCSW

Indiana
Tim Bohman

Louisiana
Royce T. Brown, M.S.

Maine
Jennifer Minthorn, M.A.

Maryland
Kenneth Stoller, M.D.

Mexico
Emilia Figueroa Guillen, M.D.

Michigan
Brian McCarroll, M.S., D.O.

Missouri
Cheryl Gardine, LCSW

Nevada
Shirley Linzy, RN, MS

New Jersey
Edward J. Higgins, M.A.

New York
Allegra Schorr

North Carolina
Kenny House, LCAS

Ohio
Keith Hochadel, M.Ed

Oklahoma
Ann Jamieson, CADC

Pennsylvania
Richard Froncillo, LCDS

South Carolina
W. Jonas Coatsworth, MA

Tennessee
Debbie Crowley

Utah
Joel L. Millard, D.S.W.

Virginia
Edward V. Ohlinger

Washington, DC
Brian Crissman

Washington
Ron Jackson, MSW

Members-at-Large
Richard Bilangi, M.S.

April 11, 2016

The Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fisher's Lane Room 13NO2B
Rockville, Maryland 20857

Reference regarding: 42 C.F.R. Part 2- Confidentiality of Alcohol and Drug Abuse
Patient Records
Regulations Proposed Rule, (SAMHSA-4162-20)

To Whom It May Concern,

I am writing on behalf of the American Association for the Treatment of Opioid Dependence, which represents approximately 1000 opioid treatment programs (OTP's) in the United States. We are submitting our comments with regard to the modification of 42 C.F.R. Part 2 which is incorporated in the Substance Abuse and Mental Health Services Administration (SAMHSA) Feb 9, 2016 proposed rule (81 Fed.Reg.6988.)

I am attaching our correspondence of June 23, 2014, which provided a response to SAMSHA following the listening session of June 11, 2014 regarding this policy matter. As indicated in this communication "we understand that the confidentiality protections were put in place more than 40 years ago and could not have anticipated changes to electronic recording keeping, Health Care Reform, or the increased abuse of prescription opioids."

Unfortunately, we are still living in a culture that actively stigmatizes and discriminates against people with substance abuse disorders, especially those with opioid addiction. SAMHSA clearly understands this discrimination based on a statement in the Executive Summary of the proposed rule. "The laws and regulations governing the confidentiality of substance abuse records were written out of great concern about potential use of substance abuse information against individuals, causing individuals with substance abuse disorders to not seek needed treatment. The disclosure of records of individuals with substance use disorders has the potential to lead to a host of negative consequences including loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution and incarcerations. The purpose of the regulation of 42 C.F.R. Part 2 is 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 the patient record than an individual with a substance use disorder who does not seek treatment." We could not state these concerns any more directly than SAMSHA has in this Executive Summary. It is also important to point out that these confidentiality regulations apply to all treatment providers, who are involved in treating substance use disorders in addition to other healthcare providers and all related parties, who come in possession of confidential patient records

We also agree with the view of the Legal Action Center that SAMHSA has struck a reasonable balance in the attempt to achieve the objectives of preserving the core confidentiality protections and rights of patients with a substance use disorder while facilitating the necessary sharing of health information as a method of providing increased quality care in a new and more integrated health delivery environment, incorporating the use of electronic exchanges of health information.

We support a more flexible consent option to address this information sharing as long as it benefits the patient. Maintaining such protections is not necessarily to provide an easier road for various vendors of electronic record keeping systems or to facilitate various research efforts in reviewing the patients' records. Maintaining the protections that have been in place for more than 40 years is still critically important to the individual patient as he/she considers whether or not to access care or to remain in care. Despite increased public knowledge of opioid addiction and overdose deaths, patients are still misunderstood and can be victims of stigma and discrimination.

Clearly, the context of treating patients is different given recent developments in the healthcare delivery system, as noted above and the changes in how individuals access such care. It is anticipated that a significant number of opioid addicted Americans will seek healthcare as they struggle with the realities of untreated opioid addiction. We have a better sense of how many Americans are addicted to opioids in rural and suburban communities in addition to a large percentage of opioid addicted individuals transitioning from prescription drug misuse to intravenous heroin abuse.

We also know that various courts, state legislatures, employers and families still do not understand why individuals would seek access to the use of medication assisted treatment for opioid addiction whether it is through the opioid treatment program or a DATA 2000 practice. There is still widespread discrimination in these areas of treating opioid addiction through child protective services and other criminal justice jurisdictions. This is an ongoing struggle for the patient who seeks to protect the confidentiality of their treatment. It determines who decides to access care and how long they remain in such care. This point is also referenced in the National Alliance for Medication Assisted Recovery (NAMA) communication as referenced in our prior correspondence of June 23, 2014. "First and foremost is the fact that prospective patients will be wary to seek treatment if they know that this knowledge will be disseminated, and through that distribution possibly become known by friends, family, employers, insurers and other providers of medical services to them". For the patient this is not an existential issue it is a matter of critical importance. Accordingly, our comments, in response to SAMSHA's proposed rule take this as our central focus in continuing to protect such patient interests.

Consent Forms and Notice Requirements

AATOD continues to support SAMHSA's protection of the core consent requirements, including the use of specific patient consent forms and the prohibition on re-disclosure.

We also support SAMHSA's approach in developing greater flexibility when such informed consents are provided by the patient allowing the OTP to share healthcare records with other networks.

AATOD is also in agreement with the Legal Action Center's position that the content and design of consent forms should be easily understood by the patients who are completing them. They should be in plain language. We also recommend that SAMHSA include an updated sample consent form and Notice of Prohibition of Re-disclosure forms in the final rule, which provide greater assistance to stakeholders which support the Part 2 confidentiality requirements.

There is also an important perspective in ensuring that the patient understands what they are signing. OTP Part 2 staff and other SUD providers need to be able to clearly explain what the patient is agreeing to. The time of executing the consent is also important depending on when the patient is being admitted to treatment. Illustratively, when a patient is initially admitted to treatment in an opioid treatment program, they are typically experiencing opioid withdrawal and are not always able to make the most informed decision through a consent process. Accordingly, SAMHSA should take this into account in providing guidance to Part 2 providers to insure a reasonable and informative consent process on behalf of the patients. This applies to all Part 2 providers, including DATA 2000 practitioners.

Qualified Service Organization

The proposed rule clarifies that "population health management" is a service that can be provided by Qualified Service Organization (QSO) to a Part 2 program and its patients through a qualified service organization agreement. This will allow patient information to be disclosed to a QSO without patient consent so that the QSO can provide the service. We advise SAMHSA to more narrowly define "population health management" so that all providers understand the "rules of engagement".

Enforcements and Education

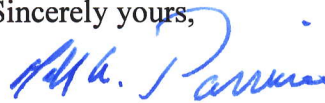
We are advising SAMHSA to ensure a strong enforcement of Part 2 requirements as a part of the final rule and what happens subsequent to the implementation of the final rule. Obviously, SAMHSA should provide training and ongoing webinars for Part 2 providers as these final rules are implemented. Such providers and patients alike will better understand new rules of engagement. This is especially important given the new opportunities for the exchange of patients' substance use disorder information. Such training should also include all systems and their representatives, who are newly accessing such patient information.

Summary

Ultimately, we understand the importance of creating greater flexibility and how patients consent to have their confidential information shared with the appropriate parties through Part 2 providers. As indicated above, it is critically important to balance these concerns with the need to protect such individuals so that the information cannot be re-disclosed without proper consent of the patient. Finally, we always need to be mindful that the patients are making critical decisions as they enter and remain in treatment. The unintended consequences of this rule cannot be further harm or exposure to those individuals who are making such important life changing decisions.

Thank you for taking these perspectives into account and thank you for creating a balanced document.

Sincerely yours,



Mark W. Parrino
President