Dear Tribal Leader:

On behalf of the Substance Abuse and Mental Health Services Administration (SAMHSA), I invite you to participate in a virtual Tribal Consultation session regarding implementation of the Confidentiality of Substance Use Disorder Patient Records regulations (42 CFR Part 2 or Part 2). The purpose of the consultation is to gain your input on the effect of Part 2 on patient care, health outcomes, and patient privacy.

The virtual Tribal Consultation session will be held on **July 31, 2018 from 2:30 pm-4:00 pm**, Eastern Standard Time. You may register for the session at: https://42cfr_tribal_listening_session.eventbrite.com

In addition to the Tribal Consultation session, SAMHSA welcomes your written comments on the implementation of Part 2 no later than September 14, 2018. Written comments may be sent by e-mail at: tribalconsultation@samhsa.hhs.gov or by mail to:

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Public Health Analyst  
Office of Tribal Affairs and Policy  
Office of Policy, Planning and Innovation  
Substance Abuse and Mental Health Services Administration  
5600 Fishers Lane, 18E09C  
Rockville, Maryland 20852

Enclosed for your reference is background information and resources on Part 2 in preparation for the Tribal Consultation session. My staff and I look forward to participating in this session and obtaining your input on the implementation of Part 2.

Sincerely,

[Signature]

Elinore F. McCance-Katz, M.D., Ph.D.  
Assistant Secretary for Mental Health and Substance Use

cc: Kathryn Power, Acting Director, Center for Substance Abuse Treatment  
Mirtha Beadle, Director, Office of Tribal Affairs and Policy
Enclosure

Background and Resources on 42 CFR Part 2

The Part 2 regulations implement Title 42, section 290dd-2, of the United States Code, pertaining to Confidentiality of Records. This statute provides that “[r]ecords of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall [...] be confidential and be disclosed only for the purposes and under the circumstances expressly authorized” by the statute or as otherwise provided. The statute further provides that such records may not be “used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient” without an appropriate court order.

The implementing regulations, 42 CFR Part 2, were first promulgated as a final rule on July 1, 1975 and substantively updated in 1987 (52 FR 21796). On February 9, 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed substantive changes to part 2 (81 FR 6987) and on January 18, 2017, SAMHSA finalized changes to these regulations (82 FR 6052). The January 2017 final rule became effective on March 21, 2017 (see 82 FR 10863, Feb. 16, 2017). This final rule was intended to “ensure that patients with substance use disorders have the ability to participate in, and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards.” The final 2017 rule made substantive changes to numerous regulatory provisions in Part 2.

Concurrently with finalizing these changes, SAMHSA issued a supplemental notice of proposed rulemaking (SNPRM) on January 18, 2017 (82 FR 5485), proposing additional changes to facilitate disclosures by lawful holders to their contractors, subcontractors and legal representative for the purposes of payment and health care operations and for carrying out an audit or evaluation and to permit disclosures by lawful holders to those conducting audits and evaluations on behalf of a governmental agency providing financial assistance to or regulatory oversight over the lawful holder. SAMHSA also sought comments on other topics, including an option for an abbreviated prohibition on re-disclosure notice. On January 3, 2018, SAMHSA finalized a rule based on the SNPRM (83 FR 239).

In response to the 2016 notice of proposed rulemaking and 2017 SNPRM, SAMHSA received many comments and suggestions from stakeholders, including tribal entities. For instance, tribal entities have suggested that SAMHSA further align Part 2 with the Health Insurance Portability and Accountability Act, ensure adequate consultation with tribal entities about Part 2 issues, provide enhanced training and technical assistance about Part 2 issues, and ensure adequate safeguards are in place with respect to consent and audit and evaluation provisions.
SAMHSA also recently heard from stakeholders at a January 31, 2018, listening session about Part 2 required by Section 11002 of the 21st Century Cures Act (see https://www.federalregister.gov/documents/2018/01/09/2018-00150/confidentiality-of-substance-use-disorder-patient-records). The law required SAMHSA to hold this meeting within one year of the final Part 2 rule becoming effective to examine the impact of Part 2 on “patient care, health outcomes, and patient privacy.”

As you consider providing comments about Part 2 before, during or subsequent to the tribal consultation, you may wish to reference the following resources:

- The January 18, 2017, final rule, which is available at: https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records. (Information from the summary section is provided above).
- The docket on Regulations.gov, which includes public comments submitted to SAMHSA on the proposed 2016 part 2 rule and SNPRM. This is available at: https://www.regulations.gov/docket?D=HHS-OS-2016-0005. These documents are for informational purposes only as the comment periods for the proposed 2016 Part 2 rule and the 2017 SNPRM are now closed.
- SAMHSA’s 42 CFR Part 2 website, which includes documents from the January 31, 2018, listening session, guidance and other information: https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines.
- The authorizing statute for Part 2, Title 42, section 290dd-2, which is available at: https://www.law.cornell.edu/uscode/text/42/290dd-2.

Any comments from the Tribal Consultation session will be fully considered on the same basis as comments SAMHSA received during the listening session.