October 21, 2019

Elinore F. McCance-Katz, Assistant Secretary
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA—Deepa Avula
5600 Fishers Lane, Room 17E41
Rockville, MD 20857.

Dear Assistant Secretary McCance-Katz:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response to the proposed rule titled, “Confidentiality of Substance Use Disorder Patient Records” as published by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the August 26, 2019 Federal Register.

SAMHSA proposes this regulation to align with advances in the health care delivery system, while retaining important privacy protections for individuals seeking treatment in federally assisted treatment programs (Part 2 programs) for substance use disorders (SUDs). SAMHSA states the desire to facilitate information exchange for safe and effective SUD care between Part 2 programs and non-part 2 providers to deliver better and safer coordinated care, while also protecting the confidentiality of individuals seeking such care.

The AAFP appreciates that SAMHSA is addressing these issues. Family physicians find themselves balancing care of people who have chronic pain with the challenges of managing opioid misuse and abuse. It is our position that the confidential relationship between physicians and patients is essential for the free flow of information necessary for sound medical care.

We applaud SAMHSA by clearly articulating that the proposed rule does not alter the basic framework for confidentiality protection of SUD patient records created by federally funded treatment programs. Rather, SAMHSA will continue to prohibit law enforcement use of SUD patient records in criminal prosecution against the patient. If finalized, this regulation will also continue to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order for good cause. The AAFP therefore supports this proposed rule as it properly protects patient privacy concerns, improves the intent of the law, and makes it less burdensome.

Only in a setting of trust can a patient share the private feelings and personal history that enable the physician to comprehend fully, to diagnose logically, and to treat properly. The AAFP supports full access by physicians to all electronic health information, as appropriate for patient care. The AAFP recognizes that data sharing between physicians and other health care providers is difficult,
particularly across state lines given differing state patient privacy/confidentiality requirements.

Regarding the Data Segmentation for Privacy (DS4P) standard and the FHIR implementation guide for Consent2Share, SAMHSA believes these tools need further development. The AAFP agrees with technical standards to support practices to enable and manage the complex requirements around the privacy and security of these types of data. **We fully support SAMHSA’s decision to not require these standards at this time.** We believe that these standards are not mature enough at this time to be required. The AAFP looks forward to maturation of these standards to dramatically reduce the burden on physicians and practices to manage the complex requirements to ensure appropriate confidentiality.

We applaud SAMHSA for seeking a greater degree of standardization. We urge SAMHSA to adhere to the AAFP’s **policy** on Patient/Physician Confidentiality regarding the privacy of medical information:

- The right to privacy is personal and fundamental.
- Medical information maintained by physicians is privileged and should remain confidential.
- The patient should have a right of access to his/her medical records and be allowed to provide identifiable additional comments or corrections. The right of access is not absolute. For example, in rare cases where full and direct disclosure to the patient might harm the patient's mental and/or physical well-being, access may be extended to his/her designated representative, preferably a physician.
- The privacy of adolescent minors should be respected. Parents should not, in some circumstances, have unrestricted access to the adolescent’s medical records. Confidentiality must be maintained particularly in areas where the adolescent has the legal right to give consent.
- Medical information may have legitimate purposes outside of the physician/patient relationship, such as, billing, quality improvement, quality assurance, population-based care, patient safety, etc. However, patients and physicians must authorize release of any personally identifiable information to other parties. Third party payer and self-insured employer policies and contracts should explicitly describe the patient information that may be released, the purpose of the information release, the party who will receive the information, and the time period limit for release. Policies and contracts should further prohibit secondary information release without specific patient and physician authorization.
- **Any disclosure of medical record information should be limited to information necessary to accomplish the purpose for which disclosure is made.** Physicians should be particularly careful to release only necessary and pertinent information when potentially inappropriate requests (e.g., "send photocopies of last five years of records") are received. Sensitive or privileged information may be excluded at the option of the physician unless the patient provides specific authorization for release. Duplication of the medical record by mechanical, digital, or other methods should not be allowed without the specific approval of the physician, taking into consideration applicable law.
- Disclosure may be made for use in conducting legal medical records audits provided that stringent safeguards to prevent release of individually identifiable information are maintained.
- Policy exceptions which permit medical records release within applicable law:
  - To another physician who is being consulted in connection with the treatment of the individual by the medical-care provider;
In compelling circumstances affecting the health and safety of an individual;
- Pursuant to a court order or statute that requires the physician to report specific diagnoses to a public health authority; and
- Pursuant to a court order or statute that requires the release of the medical record to a law enforcement agency or other legal authority.

- **Electronic health information communication systems must be equipped with appropriate safeguards (e.g., encryption; message authentication, user verification, etc.) to protect physician and patient privacy and confidentiality.** Individuals with access to electronic systems should be subject to clear, explicit, mandatory policies and procedures regarding the entry, management, storage, transmission and distribution of patient and physician information.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or rbennett@aafp.org with any questions.

Sincerely,

John S. Cullen, MD, FAAFP
Board Chair