

April 11, 2016

Substance Abuse and Mental Health
Services Administration
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, MD 20857

Re: Confidentiality of Substance Use Disorder Patient Records; Proposed Rule

To Whom It May Concern:

On behalf of our 159,000 members, we are pleased to comment on the Substance Abuse and Mental Health Services Administration (SAMHSA) proposal to expand the scope of federal regulations governing the confidentiality of patient records associated with a substance use disorder, diagnosis, treatment, or referral for treatment. We offer these comments in response to your Federal Register notice of February 9, 2016 (81 FR 6988).

Opioid pain medications—such as hydrocodone (Vicodin®), oxycodone (OxyContin® or Percocet®), morphine, and codeine—have become a leading source of drug abuse among teens and young adults. As prescribers of these painkilling medications, dentists have a role to play in helping to prevent their abuse, misuse, and diversion.

More and more dentists are providing screening, brief intervention, and referral (SBIRT) services to help patients with substance use disorders find appropriate treatment. SAMHSA has long encouraged dentists to offer SBIRT services, which dentists provide voluntarily and without compensation. Records of these encounters are kept confidential in accordance with the Health Insurance Portability and Accountability Act (HIPAA), and additional state privacy laws, as applicable.

SAMHSA is proposing to expand federal Confidentiality of Alcohol and Drug Abuse Patient Records regulations to cover any general medical facility or practice that “holds itself out” as providing, and that provides, substance use disorder diagnosis, treatment, or referral for treatment.* Historically, these regulations have applied only to facilities (and practitioners) whose primary function was to provide substance abuse treatment, and who were licensed for that purpose.

We have concerns about how the proposed confidentiality rule could impact dentists who provide SBIRT services. These services are peripheral to ordinary dental care, and the extent to which a dental office “holds itself out” as providing substance use disorder, diagnosis, treatment, or referral for treatment is unclear. It is also unclear whether and how the proposed regulations would complement or supersede the privacy and security requirements dictated by HIPAA and similar state privacy laws.

* “Diagnosis” is defined as “any reference to an individual’s substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment.”

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Enclosed you will find our supplemental comments on the proposed rule. We ask that you either exempt dentists from the proposed rule, or at least clarify the extent to which dentists who provide SBIRT services are “holding themselves out” as providing substance use disorder diagnosis, treatment, or referral for treatment. We also ask that you provide a reasonable estimate of how much it will cost the average dental practice to comply.

We understand and appreciate the need to maintain the confidentiality of personal health information that, if released, could deter an individual with a substance use disorder from seeking needed treatment. We are confident this can be done in a way that will not discourage clinicians from providing SBIRT services.

If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

/s/

Carol Gomez Summerhays, D.D.S.
President

/s/

Kathleen T. O’Loughlin, D.M.D., M.P.H.
Executive Director

CGS:KTO:rjb
Enclosure

Supplemental Comments to the
Substance Abuse and Mental Health Services Administration
on the
Confidentiality of Substance Use Disorder Patient Records; Proposed Rule
April 11, 2016

On behalf of our 159,000 members, we are pleased to offer these supplemental comments on the Substance Abuse and Mental Health Services Administration (SAMHSA) proposal to expand the scope of federal regulations governing the confidentiality of patient records associated with a substance use disorder, diagnosis, treatment, or referral for treatment. We offer these comments in response to your Federal Register notice of February 9, 2016 (81 FR 6988; RIN 0930-AA21).

The ADA is the world's oldest and largest dental professional organization, representing 159,000 dentists in the United States. The ADA is committed to the public's oral health, ethics, science and professional advancement and access to dental care for all Americans.

ADA shares the concerns that SAMHSA explains led to the laws and regulations governing confidentiality of substance abuse records: that the potential use of substance abuse information against an individual could prevent an individual with a substance use disorder from seeking needed treatment. ADA also agrees with the goal of the proposed rule as stated by SAMHSA: to ensure that patients with substance use disorders have the ability to participate in, and benefit from, new integrated health care models without fear of putting themselves at risk of adverse consequences.

However, the ADA believes that the proposed rule would cause confusion, require unnecessary and expensive duplication of compliance that is already required by HIPAA, and that compliance would be unduly burdensome. This is particularly true for dental practices, many of which are solo and small group practices. It may be impossible for such practices to determine with certainty whether the proposed rule applies to them, and if so, which patient information needs to be protected, and what the proposed rule requires them to do.

Moreover, a dental practice may find it impossible or unreasonably burdensome and expensive to configure their paper and electronic dental records systems to comply with the proposed rule. Existing and available technology may not be adaptable to support the proposed requirements, particularly in smaller practices, and applying the proposed rule to paper records would be unduly burdensome. In addition, the proposed rule may adversely impact patient care by restricting access to information necessary for treatment. Therefore, the ADA urges SAMHSA not to adopt the proposed rule, or, if the proposed rule is adopted, to exempt dental practices.

The current rule requires federally assisted substance use disorder programs ("part 2 programs") to protect the confidentiality of alcohol and drug abuse patient records. Criminal penalties apply for violations: a fine of up to \$500 for a first offense, and up to \$5,000 for each subsequent offense.

The proposed rule would expand the scope of the current rule to apply to a confusing and poorly defined array of individuals and entities that are not part 2 programs, such as:

- “Qualified service organizations,” which the proposed rule vaguely defines by providing examples rather than criteria;
- Individuals and entities in general medical facilities and practices who “hold themselves out as” providing, and who provide, substance use disorder “diagnosis,” treatment, or referral for treatment. The term “holds themselves out as” is vague and undefined, and the proposed definition of “diagnosis” causes further confusion because the proposed rule defines “diagnosis” as “any reference to an individual’s substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment,” and
- “Other lawful holders” of patient identifying information, whether or not the patient identifying information was received from a part 2 program.

These definitions are vague and confusing, which will make it difficult for dental practices to determine whether or not they must comply. Moreover, the definition of “patient identifying information” is not clear, either, so dental practices that must comply will not be able to easily and readily define the information that would require extra protection.

HIPAA currently requires covered dental practices to develop and implement compliant policies and procedures to reasonably protect patient information. HIPAA does not preempt more stringent state law, so many dental practices must comply with state law in addition to HIPAA (for example, state law may require additional protection for patient information related to a mental health diagnosis).

The proposed rule would create a confusing and burdensome third layer of compliance obligations. ADA does not believe that the proposed rule would provide additional protection for the records of patients with substance abuse disorders. If SAMHSA adopts a final rule, ADA urges SAMHSA not to apply the proposed rule to individuals and entities other than part 21 programs, and to squarely align any privacy and security requirements with HIPAA.

As an example of the confusion and duplication that could result, the proposed rule would require providing a patient, upon request, a list of entities to which a patient’s identifying information has been disclosed.

HIPAA contains a similar requirement (the “accounting of disclosures”), but the two rules would have different look-back periods and different exceptions. An individual or entity that received a request for either a SAMHSA list of disclosures or a HIPAA accounting of disclosures would be required to comb through the record to determine whether the proposed rule applies, and to comply with a confusing and contradictory set of rules in order to respond to a patient’s request.

In addition, the ADA believes the proposal to permit patients to request that the list of disclosures include the names of specific health care workers could put those workers at risk. In many health care settings, the full names of staff members are not disclosed to patients, and one reason for such a policy is to protect those workers from inappropriate contact within and outside of the facility or practice. Many facilities and practices will also lack the technology to automate tracking of disclosures to comply with both HIPAA and the proposed rule.

As another example, the proposed rule would require an entity to restrict staff access to data about substance abuse disorders. This requirement overlaps the HIPAA “minimum necessary” requirement, but does not provide the flexibility that HIPAA allows to develop and implement reasonable and appropriate safeguards.

For example, the Office for Civil Rights has stated that “...it may not be reasonable for a small, solo practitioner who has largely a paper-based records system to limit access of employees with certain functions to only limited fields in a patient record, while other employees have access to the complete record. In this case, appropriate training of employees may be sufficient.” By contrast, SAMHSA proposes a burdensome “sign-out/ sign-in” log system for paper records.

The proposed rule may have unintended consequences, such as discouraging practitioners from participating in research such as practice-based research networks out of concerns over inadvertent violations, because the rules for research may make it impossible for a provider to determine its compliance obligations. For example, a provider may not be able to determine whether a research is a HIPAA covered entity or is subject to and in compliance with the Common Rule.

Foreseeable Significant Adverse Effect on Small Businesses. In estimating the costs of the proposed changes, SAMHSA stated that it was unable to include estimates regarding the number and type of “other lawful holders” of patient identifying information, and only included part 2 programs in its analysis. ADA believes that a significant number of “other lawful holders” will be small businesses such as solo and small dental practices, and that the proposed rule would have a foreseeable, significant adverse impact on such small businesses.

ADA urges SAMHSA to estimate the costs to all entities likely to be affected by the proposed rule, particularly small facilities and practices.