NATIONAL ASSOCIATION OF PSYCHIATRIC HEALTH SYSTEMS
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August 8, 2016

Kana Enomoto, M.A.
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
ATTN: Jinhee Lee, Pharm.D.
c/o SAMHSA, 5600 Fishers Lane
Room 13E21C
Rockville, Maryland 20857

Dear Ms. Enomoto,

RE: RIN 0930–AA22: SAMHSA/HHS "Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements" (42 CFR Part 8). Docket: SAMHSA-2016-0001-0504

Dear Ms. Enomoto,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the proposed rule (SAMHSA/HHS, RIN 0930–AA22) titled "Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements" as published in the July 8, 2016, *Federal Register*.

ABOUT NAPHS

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 800 psychiatric hospitals, addiction treatment facilities, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care. Our members deliver all levels of care, including partial hospitalization services, outpatient services, residential treatment, and inpatient care.

PROPOSED RULE

On July 6, 2016, the U.S. Department of Health and Human Services (HHS) published a final rule that increases the highest patient limit for qualified physicians to treat opioid use disorder from 100 to 275. However, HHS delayed issuance of reporting requirements, pending feedback to the July 8, 2016, proposed rule on reporting requirements.

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The reporting requirements detailed in the proposed rule would require annual reporting by practitioners who are approved to treat up to 275 patients per the July 6, 2016, final rule on "Medication Assisted Treatment for Opioid Use Disorders."

In this letter, we are responding to questions initially presented in the March 30, 2016, proposed rule on MAT, as well as to new questions posed in the supplemental July 8, 2016, notice.

We acknowledge that reporting is an integral component of HHS's approach to increase access to MAT while helping to ensure that patients receive the full array of services that comprise evidence-based MAT and to minimize the risk that the medications are misused or diverted.

NAPHS COMMENTS ON QUESTIONS INITIALLY PRESENTED IN THE PROPOSED RULE

a. The average monthly caseload of patients receiving buprenorphine-based MAT, per year.

We support the reporting of the average monthly patient caseload as an essential component of accurate reporting. We suggest these data be collected and audited at least quarterly.

b. Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:
   1. **Treatment initiation**
   2. **Change in clinical status**

Psychosocial services are an essential component of evidence-based treatment of opioid addictions. We recommend that more specific information on the frequency, location, and type of psychosocial services (both referred to and received) be required of physicians with expanded buprenorphine practices. This data is an important way to distinguish providers who are engaging patients in the full range of services from providers who only provide medication. We question the use of "treatment engagement" and "change in clinical status" as the criterion for provision of psychosocial or case management services. While the type and intensity of services may change during the course of treatment, the importance of appropriate engagement in those services continues throughout.

c. Percentage of patients who had a prescription drug monitoring program query in the past month

We recommend a robust use of available prescription drug monitoring program (PDMP) queries while acknowledging that the timeliness and completeness of these databases vary geographically. These queries can serve the purposes of both ensuring that patients are not receiving buprenorphine elsewhere and/or receiving opioid pain medication somewhere else. Queries are a very important component of a diversion control program. We recommend at least quarterly (or more often) PDMP queries to avoid the potential that data would be requested by providers only once a year to meet the reporting requirement of, "percentage of patients who had a prescription monitoring program query in the past month." The importance of tying PDMP data to the actual writing of prescriptions cannot be over-emphasized.

d. Number of patients at the end of the reporting year who:
   1. **Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery**

While we acknowledge that some patients may successfully end buprenorphine treatment each year, we are concerned that the annual reporting of data, as proposed, may imply that ending medication-assisted treatment is a goal. Given that opioid use disorders are chronic diseases, patients do not *complete* treatment. Many interventions are necessary for a patient to "achieve and sustain" recovery.

   2. **Are not being seen by the provider due to referral by the provider to a more or less intensive level of care**

We recommend that this measure be divided into two questions to distinguish if the referral was to 1) a more intensive or 2) a less intensive level of care. The answers to the two questions provide very distinct and important data about the effectiveness of treatment by individual physicians. Referring an unusual number of patients to higher levels of service may indicate that the full range of expected services is not available within the practice. On the other hand, are patients successfully moving to less intense settings as a result of successful treatment at a more intense level?

3. No longer desire to continue use of buprenorphine

We support this reporting measure, as proposed.

4. Are no longer receiving buprenorphine for reasons other than 1-3.

Areas for consideration in this category may be the length of time patients were in treatment and the intensity of psychosocial interventions provided, the percentage of patients who were terminated by physicians due to treatment non-compliance, and the percentage of patients who left treatment because of financial barriers.

NAPHS COMMENTS ON NEW QUESTIONS POSED IN THE SUPPLEMENTAL NOTICE

1. **Are there different or additional elements that should be reported in order to assist HHS in ensuring compliance with the final rule?**

We recommend that the Agency strengthen its requirements for diversion-control policies in order to meet its own goal of minimizing diversion and to limit buprenorphine abuse. It is important to recognize there is a significant risk that buprenorphine can be abused. Requirements that indicate practices have diversion-control strategies in place should include such things as reporting the percentage of patients: 1) with opioid positive drug screens results; 2) with non-opioid positive drug screen results; and 3) who were subject to random buprenorphine "call back" for pill/film count.

2. Are there other ways that HHS can collect necessary information to ensure compliance with the final rule?

How practitioners will be required to report data is a very important determinant of burden. Will there be a user-friendly web-based portal? To whom will the data be reported? Frequency of reporting is also a component of burden. While we recommend quarterly reporting of several elements, we think this will actually make reporting easier because the information is more current and, hopefully, readily accessible.

Our members consistently tell us that in any reporting requirement, data that is timely, relevant, and usable compensates for perceived reporting burden. Will these data be reviewed, synthesized, reported back to the field, used for determining ongoing prescribing limits? Claims data is another important source of data. We envision most of the MAT programs should be insurance-based. Practices that are predominantly cash-based should raise red flags.

3. Would it be less burdensome to report on the number of patients in treatment for each month of the reporting period that:
   (i) Were provided counseling services at the same location as the practitioner, and how frequently those patients utilized the counseling services;

As stated above, we support this measure as counseling frequency is an important quality measurement and indicator of MAT. However, rather than report this information once per year, it should be collected at least quarterly.

(ii) The practitioner referred for counseling services at a different location?

As previously mentioned, we support tracking of counseling referrals, as well as track the frequency with which such services are utilized.

4. Would it be less burdensome to report on the number of patients at the end of the reporting year who had terminated utilization of covered medications?

It would be less burdensome to simply report a number annually, but it would do little to further the goals of these regulations. It is more important to know why the patient terminated treatment. Did the physician and patient make an informed decision that buprenorphine was no longer a required part of the patient's long-term recovery plan, did the patient decide not to pursue treatment, did the patient die?

SUMMARY

NAPHS thanks SAMHSA for its careful attention to finding the right balance between encouraging practitioners to apply for higher patient limits for prescribing buprenorphine and ensuring that they are providing high quality care. Because of the increased risks for misuse and diversion presented by these medications, we support meaningful, usable, and transparent reporting. In addition to our comments above, we ask you to address:

- Diversion control responsibilities
- How data will be reported, analyzed, and used
- How the data reporting requirements will be monitored and revised over time. An expert panel of specialists might be an effective way to evaluate this process.

Thank you for your consideration of our comments. We look forward to working with SAMHSA and the Department of Health and Human Services to develop reporting requirements that will help to ensure that medication-assisted treatment is available – as one key tool – to assist individuals living with opioid use disorders.

Sincerely,

/s/

Mark Covall
President/CEO