Programs of All-inclusive Care for the Elderly (PACE) organizations, and MMPs. For PACE organizations and MMPs, encounter data serves essentially the same purposes as it does for the MA program (for Part C and Part D risk adjustment). To 1876 Cost Plans that offer Part D coverage, CMS makes risk adjusted, capitated monthly payments for Part D.

MA organizations, Part D organizations, 1876 Cost Plans, MMPs and PACE organizations must use a CMS approved Network Service Vendor to establish connectivity with the CMS secure network for operational purposes. Once connectivity is established, these entities must submit required documents to CMS's front-end contractor to obtain security access credentials. *Form Number:* CMS–10340 (OMB control number: 0938–1152); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 733; *Total Annual Responses:* 1,068,204,429; *Total Annual Hours:* 35,618,366. (For policy questions regarding this collection contact Michael P. Massimini at 410–786–1560.)

Dated: April 22, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–08796 Filed 4–27–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder provides eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, who are state licensed and registered by the DEA to prescribe controlled substances, an exemption from certain statutory certification requirements related to training, counseling and other ancillary services (*i.e.,* psychosocial services).

DATES: This guidance takes effect April 28, 2021.

FOR FURTHER INFORMATION CONTACT: Neeraj Gandotra MD, Chief Medical Officer, Substance Abuse Mental Health Services Administration, 5600 Fishers Lane 18E67, Rockville, MD 20857, *neeraj.gandotra@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION:

A. Background

The Drug Addiction Treatment Act of 2000 (DATA 2000), which amended the Controlled Substances Act (CSA), was passed in order to improve access to treatment for Opioid Use Disorder (OUD) by allowing practitioners to prescribe approved Schedule III through V medications for OUD treatment without the need to hold a separate registration for this purpose. The CSA permits qualified practitioners to dispense certain opioid treatment medications for the treatment of OUD. Addressing the perceived barriers around prescribing buprenorphine by exempting practitioners from the certification requirements related to training, counseling and other ancillary services (*i.e.,* psychosocial services), may increase the availability of Medication-based Opioid Use Disorder Treatment (MOUD), and help address barriers to care for OUD. Buprenorphine, an FDA-approved medication for opioid use disorder, is an opioid partial agonist that produces effects such as euphoria or respiratory depression at low to moderate doses. However, these effects are weaker than full opioid agonists such as methadone and heroin. Given these properties confer a lower diversion risk, buprenorphine prescriptions are preferable to other medications in the office based setting.

B. Purpose of the Practice Guidelines

Under certain conditions, the attached Practice Guidelines exempt eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (hereinafter collectively referred to as ''practitioners''), from the certification requirements related to training, counseling and other ancillary services (*i.e.,* psychosocial services) under 21 U.S.C. 823(g)(2)(B)(i)–(ii). This action is needed in order to expand access to buprenorphine for opioid use disorder treatment. Specifically, the exemption allows these practitioners to treat up to 30 patients with OUD using buprenorphine without having to make certain training related certifications. This exemption also allows practitioners to treat patients with buprenorphine without certifying as to their capacity to provide counseling and ancillary services. This exemption specifically addresses reported barriers of the training requirement. Providers are still required to submit an application designated as a ''Notice of Intent'' in order to prescribe buprenorphine for the treatment of Opioid Use Disorder.

C. Authority: 21 U.S.C. 823(g)(2)(H)(i)(II)

Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder

Pursuant to 21 U.S.C. 823(g)(2)(H)(i)(II), the Department of Health and Human Services (HHS), issues these practice guidelines regarding the eligibility of physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (hereinafter collectively referred to as ''practitioners'') for a waiver under 21 U.S.C. 823(g)(2).

The United States faces an opioid overdose epidemic that has engendered a public health crisis and prematurely ended thousands of American lives. For the year ending in August 2020, provisional data from the Centers for Disease Control and Prevention show that overdose deaths have increased 26.8 percent compared to the previous 12 months, to more than 88,000 deaths. These deaths disproportionately affect working Americans with families, with the highest rates of opioid overdose deaths occurring in individuals between the ages of 25 and 54. Those who succumb to overdose leave spouses without partners, children without parents, and parents without children.

Medication-based treatment for opioid-use disorder (OUD), as part of a comprehensive treatment plan that may also include counseling and behavioral therapies, is an effective approach that can sustain recovery and prevent overdose. In order for a practitioner to dispense (including prescribe) buprenorphine for OUD, the practitioner must satisfy the requirements of 21 U.S.C. 823(g)(1) or 823(g)(2). Under § 823(g)(1), ''practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate [DEA] registration for that purpose.'' The ''Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both).'' *See* 21 U.S.C. 823(g)(1).

Alternatively, a practitioner may seek a waiver from this registration

requirement by submitting a notice of intent (NOI), with specific statutorily required certifications, to the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. *Id.* at § 823(g)(2)(B). Once SAMHSA approves the waiver request and notifies the Drug Enforcement Administration (DEA) of that approval, DEA issues an X-waiver identification number authorizing that practitioner to treat OUD patients with buprenorphine.

In order to be qualified for a waiver under current law, a practitioner must satisfy certain certification requirements related to training, counseling, and other ancillary services (*i.e.,* psychosocial services) that are codified under 21 U.S.C. 823(g)(2)(B)(i)–(ii). The Secretary of HHS has determined that these requirements represent a perceived barrier to prescribing buprenorphine in the United States. The Secretary of HHS, in consultation with DEA, the Administrator of the Substance Abuse and Mental Health Services Administration,[1] the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, may create exemptions from the certification requirements under 21 U.S.C. 823(g)(2) by issuing practice guidelines pursuant to 21 U.S.C. 823(g)(2)(H)(i)(II). Therefore, pursuant to this authority, HHS hereby issues the following practice guidelines exemption:

1. With respect to the prescription of medications that are covered under 21 U.S.C. 823(g)(2)(C), such as buprenorphine, practitioners licensed under state law, and who possesses a valid DEA registration under 21 U.S.C. 823(f), may become exempt from the certification requirements related to training, counseling, and other ancillary services (*i.e.,* psychosocial services) under 21 U.S.C. 823(g)(2)(B)(i)–(ii). Consistent with the applicable statute, practitioners who meet the above conditions must submit an NOI in accordance with current procedures in order to be covered under this exemption and receive a waiver. However, if a practitioner selects a patient limit of 30 in the NOI, the practitioner will not need to certify as to the training, counseling, or other ancillary services requirements listed under 21 U.S.C. 823(g)(2)(B)(i)–(ii).

2. This exemption applies to practitioners, as defined in these Guidelines, who are state licensed and DEA registered.

3. Practitioners utilizing this exemption are limited to treating no more than 30 patients at any one time. Time spent practicing under this exemption will not qualify the practitioner for a higher patient limit under 21 U.S.C. 823(g)(2)(B)(iii).

4. Physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are required to be supervised by, or work in collaboration with, a DEA registered physician if required by State law to work in collaboration with, or under the supervision of, a physician when prescribing medications for the treatment of opioid use disorder.

5. Practitioners who do not wish to practice under this exemption and its attendant 30 patient limit may seek a waiver under 21 U.S.C. 823(g)(2) per established protocols. This means that such practitioners must submit an NOI that includes all of the certifications under 21 U.S.C. 823(g)(2)(B)(i)–(iii), and qualify for a higher patient limit through one of the methods identified in 21 U.S.C. 823(g)(2)(B)(iii). More information about how to treat more than 30 patients may be found here (*https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner*).

6. This exemption applies only to the prescription of Schedule III, IV, and V drugs or combinations of such drugs, covered under 21 U.S.C. 823(g)(2)(C), such as buprenorphine. It does not apply to the prescribing, dispensing, or the use of Schedule II medications, such as methadone, for the treatment of opioid use disorders.

7. Practitioners utilizing this exemption may only treat patients who are located in states where those practitioners are licensed to treat patients unless the practitioner is an employee or contractor of a department or agency of the United States who is acting in the scope of such employment or contract, and registered under 21 U.S.C. 823(f) in any State, or is using the registration of a hospital or clinic operated by a department or agency of the United States a registered under Section 823(f). The requirements in (4) also do not apply to such employees.

Recommendations Around Training, Education, and Psychosocial Treatment

1. Recognizing the importance of practitioner education and training around the provision of comprehensive care for patients with OUD, practitioners treating patients under the exemption provided by these Practice Guidelines are strongly encouraged to utilize the HHS Buprenorphine Quick Start Guide.

2. Given the multiple challenges often faced by individuals with substance-use disorder and the high rate of psychiatric comorbidity, and evidence that psychosocial treatment may improve outcomes of treatment compliance and retention, practitioners practicing under this exemption are encouraged to provide access to psychosocial services, such as counseling, or other ancillary services, or refer as appropriate to licensed behavioral health practitioners in their communities.

3. Recognizing that substance-use disorder education is not yet uniformly integrated into medical education, colleges of medicine and residency training programs for nurses and physician assistants are strongly encouraged to develop or to continue implementing comprehensive training in substance-use disorder diagnosis and management as a component of their core, required curriculum. The SAMHSA Providers Clinical Support System may be used as a resource for technical assistance. (*https://pcssnow.org/*)

The Department, along with federal partners monitoring diversion and enforcement like DEA, will assess impact and make formal recommendations to the Secretary of Health and Human Services on whether the guideline should be continued, discontinued, or modified.

Approved: April 26, 2021.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2021–08961 Filed 4–27–21; 8:45 am]

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[1] The head of the Substance Abuse and Mental Health Services Administration is known as the Assistant Secretary for Mental Health and Substance Use following the 21st Century Cures Act (Pub. L. No: 114–255).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health & Human