

as trustee, both of Leawood, Kansas; and the Bruce L. Bachman Trust for Tyler J. Bachman, Tyler J. Bachman, as trustee, both of Shawnee, Kansas; to join the Bachman Family Control Group, a group acting in concert, to retain voting shares of First Centralia Bancshares, Inc., and thereby indirectly retain voting shares of First Heritage Bank, both of Centralia, Kansas.

Board of Governors of the Federal Reserve System, April 23, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-08872 Filed 4-27-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10326 and CMS-10340]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden. April 28, 2021.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 28, 2021.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' website address at website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Electronic Submission of Medicare Graduate Medical Education (GME) Affiliation Agreements; *Use:* Existing regulations at § 413.75(b) permit hospitals that share residents to elect to form a Medicare GME affiliated group if they are in the same or contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program by the accrediting agency. The purpose of a Medicare GME affiliated group is to provide flexibility to hospitals in structuring rotations under an aggregate full time equivalent (FTE) resident cap when they share residents. The existing

regulations at § 413.79(f)(1) specify that each hospital in a Medicare GME affiliated group must submit a Medicare GME affiliation agreement (as defined under § 413.75(b)) to the Medicare Administrative Contractor (MAC) servicing the hospital and send a copy to the Centers for Medicare and Medicaid Services' (CMS) Central Office, no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

CMS will use the information contained in electronic affiliation agreements as documentation of the existence of Medicare GME affiliations, and to verify that the affiliations being formed by teaching hospitals for the purposes of sharing their Medicare GME FTE cap slots are valid according to CMS regulations. CMS will also use these affiliation agreements as reference materials when potential issues involving specific affiliations arise. While we have used hard copies of affiliation agreements for those same purposes in the past, we implemented this electronic submission process in order to expedite and ease the process of retrieving, analyzing and evaluating affiliation agreements. *Form Number:* CMS-10326 (OMB control number: 0938-1111); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total Annual Hours:* 166. (For policy questions regarding this collection contact Shevi Marciano at 410-786-2874.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Encounter Data from MA Organizations *Use:* Section 1853(a)(3)(B) of the Act directs CMS to require MA organizations and eligible organizations with risk-sharing contracts under 1876 to "submit data regarding inpatient hospital services . . . and data regarding other services and other information as the Secretary deems necessary" in order to implement a methodology for "risk adjusting" payments made to MA organizations and other entities. Risk adjustments to enrollee monthly payments are made in order to take into account "variations in per capita costs based on [the] health status" of the Medicare beneficiaries enrolled in an MA plan.

CMS collects encounter data for beneficiaries enrolled in MA organizations, section 1876 Cost Health Maintenance Organizations (HMOs)/Competitive Medical Plans (CMPs),

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]

BILLING CODE 4120-01-P

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