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Exempt Action: Final Regulation Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC30-130
VAC Chapter title(s)	Amount, Duration and Scope of Selected Services
Action title	Removal of DEA-X Waiver
Final agency action date	February 1, 2024
Date this document prepared	February 1, 2024

This information is required for executive branch review pursuant to Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19. In addition, this information is required by the Virginia Registrar of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 et seq. of the Code of Virginia). Regulations must conform to the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Section 1262 of the Consolidated Appropriations Act (CAA), 2023, made substantial regulatory changes to remove barriers and promote access to evidence-based treatment of substance use disorders (SUD). In particular, the CAA, 2023, removed the federal requirement that practitioners obtain a special federal waiver, referred to as "X-Waiver" (or "DEA-X Waiver" or "Buprenorphine Waiver") to prescribe buprenorphine for the treatment of opioid use disorder (OUD). Note the X-Waiver is not required for prescribing buprenorphine for pain management. Accordingly, the Virginia Administrative Code is being amended to allow providers who have a current license to practice and prescribe, as well as a Drug Enforcement Administration (DEA)

registration authorizing the prescribing of Schedule III drugs, to prescribe buprenorphine for the treatment of opioid use disorder without the federal X-Waiver since it has since been eliminated.

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DMAS submitted a state plan amendment (SPA) to the Centers for Medicare & Medicaid Services (CMS) that removed the X-Waiver requirement. The SPA was approved on September 21, 2023, and this regulatory action incorporates the changes in the Virginia Administrative Code.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The Code of Virginia § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance and to promulgate regulations. The Code of Virginia § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

Section 1262 of the Consolidated Appropriations Act, 2023, eliminated the federal requirement that practitioners obtain a X-Waiver to prescribe buprenorphine to treat patients with OUD. Accordingly, the Virginia Administrative Code is being amended to allow providers who have a current license to practice and prescribe, as well as a DEA registration authorizing the prescribing of Schedule III drugs, to prescribe buprenorphine for the treatment of OUD without the federal X-Waiver. Specifically, this regulatory action amends text in 12 VAC 30-130-5020, 12 VAC 30-130-5050, 12 VAC 30-130-5060, 12 VAC 30-130-5090, 12 VAC 30-130-5100, 12 VAC 30-130-5120, 12 VAC 30-130-5130, 12 VAC 30-130-5140, and 12 VAC 30-130-5150.

This action is exempt from the regulatory process in accordance with Va. Code 2.2-4006(A)(4)(c), as it is necessary to meet the requirements of federal law or regulations.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

DMAS has submitted Final Exempt changes to 12 VAC 30-130-5020, "Definitions," 12 VAC 30-130-5050, "Covered services: clinic services - opioid treatment program services," 12 VAC 30-130-5060, "Covered services: clinic services - preferred office-based addiction treatment," 12 VAC 30-130-5090, "Covered services: community based services - intensive outpatient services (ASAM Level 2.1)," 12 VAC 30-130-5100, "Covered services: community based care - partial hospitalization services (ASAM Level 2.5)," 12 VAC 30-130-5120, "Covered services: clinically managed population - specific high intensity residential service (ASAM Level 3.3)," 12 VAC 30-130-5130, "Covered services: clinically managed high intensity residential services (adult) and clinically managed medium intensity residential services," 12 VAC 30-130-5140, "Covered services: medically monitored intensive inpatient services (adult) and medically monitored high

intensity inpatient services (adolescent)," and 12 VAC 30-130-5150, "Covered services: medically managed intensive inpatient services (ASAM Level 4.0)" in order to meet the Section 1262 of the Consolidated Appropriations Act, 2023, mandate.

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