on the date on which all required clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or §11.48, as applicable, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1). If no clinical trial results information is required to be submitted, a responsible party's obligation to correct or address errors ends on the date on which all required clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or §11.28, as applicable, and corrections have been made or addressed in response to any electronic notice received under §11.64(b)(1).

(3) Compliance with the quality control review process, including the requirements of this section, does not constitute a legal defense to enforcement pursuant to section 301(jj) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331(jj)), section 303(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 333(f)(3)), or any other Federal law.

[81 FR 65138, Sept. 21, 2016, as amended at 89 FR 97559, Dec. 9, 2024]

Subpart E—Potential Legal Consequences of Non-Compliance

§11.66 What are potential legal consequences of not complying with the requirements of this part?

(a) *Civil or criminal judicial actions.* Failure to comply with the requirements of this part, issued under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), is a prohibited act under one or more provisions of section 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(jj)):

(1) Failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service (42 U.S.C. 282(j)(5)(B)) that all applicable requirements of section 402(j) have been met, or knowingly submitting a false certification under section 402(j)(5)(B), is a prohibited act under section 301(jj)(1) of the Federal Food, Drug, and Cosmetic Act.

(2) Failure to submit clinical trial information required under section 402(j) of the Public Health Service Act is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act.

(3) Submission of clinical trial information under section 402(j) that is false or misleading in any particular is a prohibited act under section 301(jj)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Civil monetary penalty actions.* Any person who violates section 301(jj) of the Federal Food, Drug, and Cosmetic Act is subject to civil monetary penalties under section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(3)).

(c) *Grant funding actions.* Under section 402(j)(5)(A) of the Public Health Service Act (42 U.S.C. 282(j)(5)(A)), if an applicable clinical trial is funded in whole or part by the Department of Health and Human Services, any required grant or progress report forms must include a certification that the responsible party has made all required registration and results submissions. If it is not verified that the required registration and results clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted, any remaining funding for a grant or funding for a future grant to such grantee will not be released. If the head of an HHS agency verifies that a grantee has not submitted such required clinical trial information, the agency head will provide notice to the grantee of the noncompliance and allow the grantee 30 days to correct the non-compliance and submit the required clinical trial information.

PART 12—TELEMEDICINE FLEXIBILITIES

Subpart A—Special Exceptions Related to Telemedicine

Sec.

Subpart B—Telemedicine Prescribing

AUTHORITY: 21 U.S.C. 802(54)(G).

SOURCE: 88 FR 30042, May 10, 2023, unless otherwise noted.

EFFECTIVE DATE NOTE: At 88 FR 30042, May 10, 2023, part 12 was added, effective May 11, 2023 through Nov. 11, 2024. At 88 FR 69879, Oct. 10, 2023, the expiration date was extended to Dec. 31, 2024.

Subpart A—Special Exceptions Related to Telemedicine

§ 12.1 Temporary extension of certain COVID–19 telemedicine flexibilities for prescription of controlled medications.

(a) This section is in effect until the end of the day December 31, 2025. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2025.

(b) During the period May 12, 2023, through December 31, 2025, a Drug Enforcement Administration (DEA)-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (c) of this section are met.

(c) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraph (b) of this section if all of the following conditions are met:

(1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);

(3) The practitioner is:

(i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d); and

(4) The prescription is consistent with all other requirements of 21 CFR part 1306.

[88 FR 30042, May 10, 2023, as amended at 88 FR 69883, Oct. 10, 2023; 89 FR 91257, Nov. 19, 2024]

EFFECTIVE DATE NOTE: At 89 FR 91257, Nov. 19, 2024, §12.1 was amended, effective Jan. 1, 2025 through Dec. 31, 2025.

§ 12.2 [Reserved]

Subpart B—Telemedicine Prescribing

SOURCE: 90 FR 6523, Jan. 17, 2025, unless otherwise noted.

EFFECTIVE DATE NOTE: At 90 FR 6523, Jan. 17, 2025, subpart B was added, this amendment was delayed until Mar. 21, 2025 at 90 FR 9841, Feb. 19, 2025, and was further delayed until Dec. 31, 2025 published at 90 FR 13410, Mar. 24, 2025.

§ 12.3 Telemedicine prescribing of schedule III–V medications for the treatment of Opioid Use Disorder.

(a) For purposes of this section, terms defined in 21 CFR part 1300, elsewhere in 21 CFR chapter II, or in 21 U.S.C. 802 and 829 shall have the definitions set forth therein.

(b) A practitioner may issue a prescription for schedule III–V controlled substances listed in 42 CFR 8.12(h)(2) as approved by the Food and Drug Administration (FDA) for use in the treatment of Opioid Use Disorder (OUD), defined as the use of an effective medication such as buprenorphine to treat OUD, pursuant to a communication between the prescribing practitioner and the patient using an interactive telecommunications system, including an audio-only telecommunications system, as described in 42 CFR 410.78(a)(3), if the following conditions are met:

(1) *Prescription drug monitoring program review.* The prescribing practitioner must be authorized to access the applicable prescription drug monitoring program (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter. The prescribing practitioner shall

review such data regarding any controlled medication prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The prescribing practitioner shall ensure the date and time of such a review is annotated in the patient's electronic health record (EHR) or paper record. This review, or attempted review, must be conducted prior to issuing a prescription in a manner authorized under this section.

(2) *Time limit.* The practitioner may issue prescriptions to the patient pursuant to this section for a period not to exceed six calendar months beginning on the date the first prescription is issued. The practitioner may issue additional prescriptions to the patient for schedule III–V controlled substances approved by the FDA for use in the treatment of OUD either:

(i) As authorized by 21 U.S.C. 829(e), including pursuant to any other form of telemedicine as defined in 21 U.S.C. 802(54) or pursuant to practices as determined by regulation issued pursuant to 21 U.S.C. 829(e)(3)(B); or

(ii) After the prescribing practitioner has conducted at least one in-person medical evaluation of the patient, as defined in 21 U.S.C. 829(e)(2)(B).

(3) *PDMP inaccessible or unavailable.* If the PDMP data is inaccessible or unavailable for any reason, the prescribing practitioner shall annotate in the patient's EHR or paper record the date and time that an attempt to view the PDMP data was made and the reason the data could not be reviewed. A practitioner may prescribe a seven-day supply of medication and must perform another PDMP review before prescribing another seven-day supply. Each time the PDMP is reviewed or attempted to be reviewed, the date and time must be annotated in the patient's EHR. A seven-day supply prescribed pursuant to this paragraph (b)(3) counts toward the time limit described in paragraph (b)(2) of this section.

(4) *Pharmacy identification requirement.* The pharmacist shall verify the identity of the patient prior to filling a controlled medication prescription issued under the authority of this section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any qualifying ''ultimate user'' as defined in 21 U.S.C. 802(27) prior to filling the prescription.

(5) *Prescription only for treatment of OUD.* Controlled medication prescriptions issued pursuant to this section may only be issued for the treatment of OUD.

(6) *Authorization to prescribe.* The practitioner must be:

(i) Authorized under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled medication specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d).

(7) *Consistent with general prescription requirements.* The issuance of the controlled substance prescription otherwise complies with the requirements set forth in 21 CFR part 1306.

§ 12.4 Telemedicine prescribing of schedule II–V medications by the Department of Veterans Affairs practitioners.

A practitioner may prescribe controlled substance(s) to a patient via the practice of telemedicine under 21 CFR 1300.04(i)(7) if all the following conditions are met:

(a) The practitioner is:

(1) An employee or contractor of the Department of Veterans Affairs (VA) who is acting in the scope of such employment or contract, and registered under section 303(g) of the Controlled Substances Act (Act) (21 U.S.C. 823(g)) (21 CFR 1301.13) in any state or is utilizing the registration of a hospital or clinic operated by the VA registered under section 303(f);

(2) Prescribing to a patient who has previously received, at any time, an in-person medical evaluation by any VA practitioner who at the time of the in-person medical evaluation was acting within the scope of their VA employment or contract and had prescribing authority, or would reasonably be expected to have prescribing authority

based on their credentials (*e.g.*, medical doctor) or organizational role (*e.g.*, primary care provider), as described in paragraph (a)(1) of this section;

(3) Not a contracted practitioner located outside a VA facility or clinic providing care via the community care network or conducting disability compensation evaluations; and

(4) Prescribing a controlled substance(s) for a legitimate medical purpose in the usual course of professional practice, and in accordance with applicable Federal and State law(s).

(b) Prior to prescribing, the practitioner must conduct a review of both the VA EHR, to include the VA's internal prescription database, and the PDMP data of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) for controlled substance prescription(s) for the patient's previous twelve (12) months preceding the controlled substance prescription(s), or if less than a year of data is available, for the entire prescription period.

(1) Should either the patient's VA electronic health record, to include the VA's internal prescription database, or the PDMP data of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) be unavailable or non-operational, for any reason, the VA practitioner must limit the prescription to a 7-day supply. Once the VA's internal prescription database and the PDMP are available or operational, a review of the databases as outlined in this paragraph (b) must be completed to continue prescribing the controlled substance(s) to the VA patient.

(2) If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the VA practitioner must review the VA internal prescription database prior to issuing a controlled substance prescription. A prescription may extend beyond 7 days under this circumstance.

(3) The VA practitioner must annotate in the VA patient's EHR their attempts to access the PDMP data of the state in which the patient is located, and VA internal prescription database data. If the prescribing VA practitioner fails to access the PDMP data of the state in which the patient is located or VA internal prescription database data as described in paragraph (b)(1) of this section, the VA practitioner must annotate in the VA patient's EHR the dates and times that the VA practitioner attempted to gain access, the reason why the VA practitioner was unable to gain access, and any follow-up attempts made to gain access to the system. The attempts must be recorded in accordance with the VA's internal policies and recordkeeping requirements.

(c) The controlled substance prescription(s) is otherwise in conformity with the requirements of the Act and 21 CFR chapter II.

EFFECTIVE DATE NOTE: At 90 FR 6539, Jan. 17, 2025, §12.4 was added, This amendment was delayed until Mar. 21, 2025 at 90 FR 9841, Feb. 19, 2025, Amendment further delayed until Dec. 31, 2025 published at 90 FR 13410, Mar. 24, 2025.