DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA–407]

RIN 1117–AB40 and 1117–AB78

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications

AGENCY: Drug Enforcement Administration, Department of Justice; Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Temporary rule.

SUMMARY: On March 1, 2023 the Drug Enforcement Administration (DEA), in concert with the Department of Health and Human Services (HHS), promulgated two notices of proposed rulemakings (NPRMs) soliciting comments on proposals to allow for prescribing of controlled medications pursuant to the practice of telemedicine in instances where the prescribing practitioner has never conducted an in-person medical evaluation of the patient. Those NPRMs resulted in 38,369 public comments, which are being closely reviewed. DEA, in concert with HHS, is considering revisions to the proposed rules set forth in the NPRMs. In the meantime, and following initial review of the comments received, DEA, jointly with the Substance Abuse and Mental Health Services Administration (SAMHSA), is issuing this temporary rule to extend certain exceptions granted to existing DEA regulations in March 2020 as a result of the COVID–19 Public Health Emergency (COVID–19 PHE), in order to avoid lapses in care for patients. Ultimately, there will be a final set of regulations permitting the practice of telemedicine under circumstances that are consistent with public health, safety, and effective controls against diversion.

DATES: This rule is effective May 11, 2023, through November 11, 2024.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Background

Overview

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act), a prescribing practitioner—subject to certain exceptions—may prescribe controlled medications to a patient only after conducting an in-person evaluation of that patient. In response to the COVID–19 Public Health Emergency (COVID–19 PHE) as declared by the Secretary (the Secretary) of the Department of Health and Human Services (HHS) on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), the Drug Enforcement Administration (DEA) granted temporary exceptions to the Ryan Haight Act and DEA's implementing regulations under 21 U.S.C. 802(54)(D), thereby allowing the prescribing of controlled medications via telemedicine encounters—even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient—in order to prevent lapses in care. These telemedicine flexibilities authorize practitioners to prescribe schedule II–V controlled medications via audio-video telemedicine encounters, including schedule III–V narcotic controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, without requiring an in-person medical evaluation, provided that such prescriptions otherwise comply with the requirements outlined in DEA guidance documents, DEA regulations, and applicable Federal and State law. DEA granted those temporary exceptions to the Ryan Haight Act and DEA's implementing regulations via two letters published in March 2020:

- A March 25, 2020 ''Dear Registrant'' letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division (the McDermott Letter); [1] and
- A March 31, 2020 ''Dear Registrant'' letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division (the Prevoznik Letter).[2]

On March 1, 2023, DEA, in concert with HHS, promulgated two NPRMs in the **Federal Register**—''Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation'' [3] (the General Telemedicine Rule) and ''Expansion of induction of buprenorphine via telemedicine encounter'' [4] (the Buprenorphine Rule)—which proposed to expand patient access to prescriptions for controlled medications via telemedicine encounters relative to the pre-COVID–19 PHE landscape. The purpose of the two proposed rules was to make permanent some of the telemedicine flexibilities established during the COVID–19 PHE in order to facilitate patient access to controlled medications via telemedicine when consistent with public health and safety, while maintaining effective controls against diversion. The comment period for these two NPRMs closed on March 31, 2023. Those NPRMs generated a total of 38,369 public comments—35,454 comments on the General Telemedicine Rule and 2,915 comments on the Buprenorphine Rule.

SAMHSA and DEA strongly support policies that promote access to effective and safe treatment for opioid use disorder, including through telemedicine platforms, and ensuring continued access to necessary controlled medications past the COVID–PHE.

After reviewing those comments, DEA, jointly with SAMHSA, is issuing this temporary rule to effectuate the following:

- The full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID–19 PHE will remain in place through November 11, 2023.
- Additionally, for any practitioner-patient telemedicine relationships that have been or will be established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID–19 PHE will continue to be permitted via a one-year grace period through November 11, 2024. In other words, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted until November 11, 2024.

[1] William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (March 25, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf.*

[2] Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (March 31, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.*

[3] 88 FR 12,875 (Mar. 1, 2023).

[4] 88 FR 12,890 (Mar. 1, 2023).

In the meantime, DEA is continuing to carefully evaluate the comments received on the NPRMs and anticipates implementation of a final set of regulations permitting the practice of telemedicine under circumstances that are consistent with public health, safety, and effective controls against diversion; the goal of this temporary rule is to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions, as well as allowing adequate time for providers to come into compliance with any new standards or safeguards that DEA and/or SAMHSA promulgate in one or more final rules.

History of This Rulemaking

In the General Telemedicine Rule NPRM, DEA, in concert with HHS, proposed to extend the COVID–19 PHE telemedicine flexibilities for 180 days beyond the end of the COVID–19 PHE for practitioner-patient relationships established via telemedicine encounters during the COVID–19 PHE.[5] Within the ''Request for Comments'' section, DEA requested comments concerning whether any additional regulatory provisions were warranted to ensure appropriate access to care, and noted that the proposed rule was designed to ensure that patients do not experience lapses in care.[6] The ''Request for Comments'' section also explained that the proposed rule was designed to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID–19 PHE.[7] In response to the proposed rule and these requests for comments, DEA received hundreds of comments in support of further extending, beyond the initial period of 180 days, the telemedicine flexibilities for registrants who established practitioner-patient relationships via telemedicine encounters during the COVID–19 PHE. DEA also received thousands of comments supporting a similar extension of the COVID–19 PHE telemedicine flexibilities, for at least 180 days, for practitioner-patient relationships that will begin after the end of the COVID–19 PHE.

II. Legal Authority

The Ryan Haight Act amended the Controlled Substances Act (CSA) to generally require that the dispensing of controlled medications by means of the internet be predicated on a valid prescription involving at least one in-person medical evaluation. At the same time, it also established excepted categories of telemedicine pursuant to which a practitioner may prescribe controlled medications for a patient despite never having evaluated that patient in person, provided that, among other things, such practice is in accordance with applicable Federal and State laws.[8]

One of these categories authorizes the Attorney General and the Secretary of Health and Human Services to jointly promulgate rules that would allow practitioners to prescribe medications for patients via telemedicine without having had an in-person evaluation when such telemedicine practice is in accordance with applicable Federal and State laws, uses an approved telecommunications system, and is ''conducted under . . . circumstances that the[y have] . . . determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.'' [9]

Pursuant to this authority, and in response to comments received on the NPRMs, DEA, jointly with SAMHSA, is hereby promulgating a temporary rule specifying certain circumstances under which practitioners may prescribe controlled medications, for a narrow time period, to patients whom the practitioner has never evaluated in person. This temporary rule covers the portions of the NPRM related to extensions of the telemedicine flexibilities in place during the COVID–19 PHE, and it extends, through November 11, 2023, the telemedicine flexibilities that have been in place since March 2020 for prescribing controlled medications via the practice of telemedicine. This temporary rule also extends the COVID–19 PHE telemedicine flexibilities through November 11, 2024, as applied to any practitioner-patient relationships established via telemedicine encounters on or before November 11, 2023. In other words, as long as a practitioner and patient have established a telemedicine relationship on or before November 11, 2023, the pandemic telemedicine flexibilities will be extended through November 11, 2024, as to that established relationship. These telemedicine flexibilities will not be applicable to any practitioner-patient relationships established after November 11, 2023. As noted previously, DEA and/or SAMHSA anticipate implementing a final set of regulations permitting the practice of telemedicine under circumstances that are consistent with public health, safety, and effective controls against diversion. However, given the impending end of the COVID–19 PHE and in recognition of comments received,[10] DEA, jointly with SAMHSA, has elected to extend those flexibilities to avoid lapses in care.

As explained further below, because this is a temporary extension of flexibilities that existed during the COVID–19 PHE, DEA and SAMHSA have determined that this temporary rule is consistent ''with effective controls against diversion and otherwise consistent with the public health and safety'' as required under 21 U.S.C. 802(54)(G). DEA, jointly with SAMHSA, is promulgating this temporary rule pursuant to 21 U.S.C. 802(54)(G).

DEA is issuing these regulatory changes jointly with SAMHSA. SAMHSA concurs with this rule. SAMHSA also has advised DEA that no additional rulemaking by SAMHSA is necessary as it pertains to the promulgation of these provisions pursuant to 21 U.S.C. 802(54)(G).

III. Purpose and Need for Regulatory Changes

The purpose of this rulemaking is to extend for a limited period of time the telemedicine flexibilities that existed during the COVID–19 PHE in order to:

- Facilitate continuity of care for telemedicine relationships established via telemedicine during the COVID–19 PHE;
- For relationships established both during the COVID–19 PHE and those established shortly after, prevent backlogs with respect to in-person medical evaluations in the months shortly before and after the expiration of the COVID–19 PHE and ensure the availability of telemedicine for practitioners and patients that have come to rely on it;
- Address the urgent public health need for continued access to the initiation of buprenorphine as medication for opioid use disorder in the context of the continuing opioid public health crisis;
- Allow patients, practitioners, pharmacists, service providers, and other stakeholders sufficient time to

[5] 88 FR 12,879, 12888 (Mar. 1, 2023).

[6] *See* 88 FR at 12,882.

[7] *See id.*

[8] 21 U.S.C. 802(54)(A)–(G). The Attorney General has delegated his rulemaking authority under this provision to the Administrator of DEA via 28 CFR 0.100. The Secretary of HHS delegated his rulemaking authority under 21 U.S.C. 802(54)(G) to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration on May 4, 2023.

[9] 21 U.S.C. 802(54)(G).

[10] It is anticipated that the COVID–19 PHE will expire on May 11, 2023.

prepare for the implementation of any future regulations that apply to prescribing of controlled medications via telemedicine;

• Enable DEA, jointly with SAMHSA, to thoroughly review and respond to the 38,369 comments they received in response to the two NPRMs; and

• Enable DEA, jointly with SAMHSA, to conduct a thorough evaluation of regulatory alternatives in order to promulgate regulations that most effectively expand access to telemedicine encounters in a manner that is consistent with public health and safety, while maintaining effective controls against diversion.

IV. Summary of Temporary Rule Changes

This rule adds new 21 CFR 1307.41 and 42 CFR 12.1, effective from the day after the public health emergency ends, which is expected to be May 12, 2023, through November 11, 2024. Paragraph (a) states that this temporary rule is in effect until November 11, 2024, and will expire at the end of that day. It also states that the authorization granted in paragraph (c) expires at the end of November 11, 2023.

Paragraph (b) states that a practitioner and patient have a ''telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities'' if the practitioner issued the patient a prescription for controlled medications pursuant to the telemedicine flexibilities that were available during the COVID–19 PHE and extended through November 11, 2023 by this temporary rule.

Paragraph (c) extends the COVID–19 telemedicine prescribing flexibilities for six months, from May 12, 2023 through November 11, 2023, provided all of the conditions listed in paragraph (e) are met.

Paragraph (d) provides for a partial extension of those telehealth flexibilities through November 11, 2024, but only with respect to patients with whom the prescribing practitioner has a telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities on or before November 11, 2023, as defined in paragraph (b) and provided all the conditions listed in paragraph (e) are met.

Paragraph (e) describes the conditions which must be met for practitioners to issue prescriptions pursuant to paragraphs (c) and (d). All such requirements were in place during the COVID–19 PHE:

• First, the prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.[11]

• Second, the prescription must be 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)—that is, audio and video equipment permitting two-way, real-time interactive communication or, for prescriptions to treat a mental health disorder—which include, but are not limited to, prescriptions for buprenorphine for opioid use disorder—a two-way, real-time audio-only communication if the distant site physician or practitioner is technically capable of using an interactive audio-video telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology.[12]

• Third, the practitioner must be authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled medications specified on the prescription or exempt from obtaining a registration to dispense controlled medications under 21 U.S.C. 822(d).[13]

• Fourth, the prescription must be consistent with all other requirements of 21 CFR part 1306.[14]

V. Discussion of Comments

Comment: DEA received several thousand comments supporting an extension of the COVID–19 PHE telemedicine flexibilities for all practitioner-patient telemedicine relationships, not only those established during the COVID–19 PHE. Commenters raised the following arguments in support of extending the COVID–19 telehealth flexibilities for all practitioner-patient telemedicine relationships:

• If DEA, jointly with SAMHSA, were to extend the telemedicine flexibilities to the dates suggested by commenters, such as until December 31, 2024, it would provide DEA, SAMHSA, and other agencies with a longer timeframe to educate patients, practitioners, and pharmacies about any changes in regulatory requirements and would be consistent with certain other statutory extensions of healthcare-related flexibilities beyond the end of the COVID–19 PHE.[15]

• In the absence of an extension, practitioners could be inundated with in-person evaluation requests and backlogs for in-person medical evaluations might result. Along similar lines, practitioner infrastructure might prove inadequate if practitioners were inundated with in-person evaluation requests over a short period of time.

DEA also received several comments generally opposing an extension of the telemedicine flexibilities. Commenters raised the following arguments in support of this position:

• The telemedicine flexibilities that existed during the COVID–19 PHE increased diversion and overprescribing of some controlled medications, particularly as a result of certain telemedicine companies that do not conduct or require *bona fide* medical evaluations of patients prior to issuance of controlled medication prescriptions.

Response: DEA and SAMHSA largely agree with the arguments asserted in the comments on this issue for broadening the extension to all practitioner-patient relationships for an additional six-month period, not only for those relationships established during the COVID–19 PHE. Accordingly, at this time, DEA, jointly with SAMHSA, has elected to extend the telemedicine flexibilities not only for practitioner-patient relationships established via telemedicine encounters during the COVID–19 PHE, but also for those relationships established via telemedicine encounters after the end of the COVID–19 PHE, for a period of six months, through November 11, 2023. It is planned that one or more final rules will be issued based on the two proposed rules published on March 1, 2023.

DEA and SAMHSA agree that immediately ceasing the COVID–19 telemedicine flexibilities for relationships established both during and following the end of the COVID–19 PHE would jeopardize continuity of patient care. In particular, without a general extension, patients seeking

[11] *See* 21 CFR 1306.04(a); Prevoznik letter at 2. Though not specifically mentioned in the McDermott letter, the McDermott letter did not provide an exemption to the requirement in 21 CFR 1306.04(a) that every prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

[12] *See* 42 CFR 410.78(a)(3); McDermott Letter at 2 (citing 21 U.S.C. 802(54)(D)); Prevoznik Letter at 2.

[13] *See* McDermott Letter at 1.

[14] Both the McDermott Letter and the Prevoznik Letter specified which requirements of Part 1306 from which practitioners were exempted. Requirements not exempted in the letters remained in effect.

[15] Some commenters noted that Section 4113 of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022 (Division FF of the Consolidated Appropriations Act, 2023) has extended some flexibilities to Medicare beneficiaries through December 31, 2024 and asked for a similar extension with respect to telemedicine prescribing flexibilities for controlled medications. *See* Consolidated Appropriations Act, 2023, Public Law 117–328, Div. FF § 4113, Dec. 29, 2022, 136 Stat. 4459, 5898.

prescriptions of controlled medications following expiration of the COVID–19 PHE as a result of existing or new practitioner-patient telemedicine relationships might be met with backlogs, as practitioners might be inundated with requests for in-person medical evaluations. In addition, practitioners might find it difficult to manage the period shortly after the COVID–19 PHE expires with respect to new patients in the absence of a short-term extension of the flexibilities that have existed since March 2020.

DEA and SAMHSA anticipate the issuance of final rules extending certain telemedicine flexibilities on a permanent basis. At this time, DEA does not believe it would be consistent with effective controls against diversion to grant a longer extension—beyond this initial six-month period—for practitioner-patient relationships that begin after the end of the COVID–19 PHE. This is an effort to disincentivize the creation of telemedicine companies that may seek to engage in problematic prescribing practices. By only extending the flexibilities for a short period, the six-month extension would be unlikely to incentivize the investment necessary to develop new telemedicine companies that might encourage or enable problematic prescribing practices. DEA stresses that, while certain telemedicine companies may engage in problematic behavior, many telemedicine companies are engaged in good faith, patient-centered prescribing practices. DEA looks forward to working with them—and future companies in this space—to further enhance patient access to needed medications when telemedicine prescriptions are appropriate and issued in the usual course of professional practice following *bona fide* medical evaluations.[16] In the meantime, DEA is actively investigating certain telemedicine companies that it believes may have engaged in problematic prescribing practices.

In addition, and as noted above, DEA received 38,369 comments on the General Telemedicine Rule and the Buprenorphine Rule. DEA is currently in the process of closely evaluating those comments, as well as all regulatory options available, but anticipates that this review will extend beyond the end of the COVID–19 PHE, which is expected to expire at the end of the day on May 11, 2023. Ultimately, DEA and SAMHSA anticipate implementing a final set of regulations permitting the practice of telemedicine under circumstances that are consistent with public health and safety, while maintaining effective controls against diversion. In the meantime, given the limited duration of this extension of the telemedicine flexibilities and legitimate concerns regarding patient access to care following the end of the COVID–19 PHE, DEA, jointly with SAMHSA, finds that the limited extension of the telemedicine flexibilities that existed during the COVID–19 PHE is consistent with public health, safety, and effective controls against diversion.

Comment: DEA also received several hundred comments supporting a further grace period—beyond 180 days—for requiring an in-person evaluation for practitioner-patient telemedicine relationships established during the COVID–19 PHE. Commenters raised the following arguments in support of this position:

- If DEA, jointly with SAMHSA, were to extend the telemedicine flexibilities for a longer period, such as until December 31, 2024, it would provide DEA, SAMHSA, and other agencies with a longer timeframe to educate patients and practitioners that have already established relationships and come to rely on the COVID–19 PHE flexibilities about any changes in regulatory requirements. Such a date would also be consistent with certain other statutory extensions of healthcare-related flexibilities beyond the end of the COVID–19 PHE.[17]
- In the absence of a grace period, practitioners could be inundated with in-person evaluation requests and backlogs for in-person medical evaluations might result.
- It may prove difficult for patients to obtain in-person medical evaluations within 180 days with practitioners with whom they have established legitimate telemedicine relationships given constraints on such patients' ability to travel, including the distance between the patient and practitioner, the need to request time off from work, or difficulty obtaining childcare.

DEA also received several comments generally opposing a grace period with respect to the telemedicine prescribing flexibilities. Commenters raised the following arguments in support of this position:

- The telemedicine flexibilities that existed during the COVID–19 PHE may have increased diversion and overprescribing of some controlled medications, particularly as a result of for-profit telemedicine companies that do not conduct or require *bona fide* medical evaluations of patients prior to issuance of controlled medication prescriptions.

Response: DEA and SAMHSA largely agree with the arguments asserted in the comments on this issue for lengthening the grace period for relationships that began during the COVID–19 PHE or that will begin during the extension granted for the next six months. DEA and SAMHSA are concerned that a 180-day period would be too brief an exemption for practitioner-patient telemedicine relationships established during the COVID–19 pandemic, as both practitioners and patients may have come to rely on the ability to meet via telemedicine. In addition, with a grace period of only 180 days, practitioners—including those with significant numbers of telemedicine patients—might find it difficult to meet with all patients with whom they had developed a telehealth relationship during the COVID–19 PHE or in the six months after. Accordingly, for those practitioner-patient relationships established between the start of the COVID–19 PHE and November 11, 2023, DEA, jointly with SAMHSA, is permitting a grace period for the COVID–19 PHE telehealth flexibilities through November 11, 2024, as they have determined that doing so would be consistent with public health and safety as required under 21 U.S.C. 802(54)(G).

With respect to the arguments against the grace period, DEA agrees with commenters who noted that there were instances of overprescribing and potentially diversion during the COVID–19 PHE, particularly with respect to certain for-profit telemedicine companies. However, DEA believes that authorizing an initial time-limited grace period for the telemedicine flexibilities as they have existed during the COVID–19 PHE for practitioner-patient telemedicine relationships established during the COVID–19 PHE and for the six months thereafter would be consistent with effective controls against diversion. DEA believes this limited extension through November 11, 2024, would be unlikely to incentivize the investment necessary to further develop telemedicine companies that have already encouraged and enabled

[16] The Ryan Haight Act makes it unlawful for an entity to knowingly or intentionally cause the internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by law. *See* 21 U.S.C. 841(h)(2)(C). In spite of this clear statutory prohibition, DEA is aware of certain rogue websites that were designed primarily to make money by selling prescription drugs containing controlled substances without *bona fide* medical evaluations for patients.

[17] Some commenters noted that Section 4113 of the Consolidated Appropriations Act of 2023 has extended some flexibilities to Medicare beneficiaries through December 31, 2024 and asked for a similar extension with respect to telemedicine prescribing flexibilities for controlled medications. *See* Consolidated Appropriations Act, 2023, Public Law 117–328, Div. FF § 4113, Dec. 29, 2022, 136 Stat. 4459, 5898.

these problematic prescribing practices during the COVID–19 PHE. Accordingly, at this time, DEA, jointly with SAMHSA, finds that the one-year grace period granted herein with respect to relationships established between the start of the COVID–19 PHE and November 11, 2023, is consistent with effective controls against diversion as required under 21 U.S.C. 802(54)(G).

VI. Regulatory Analyses

Administrative Procedure Act

DEA has considered the public comments it received on the two proposed rules, regarding the continuation of the flexibilities that will be implemented by this temporary rule. An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA). Under the APA, agencies must generally provide a 30-day delayed effective date for final rules.[18] An agency may dispense with the 30-day delayed effective date requirement ''for good cause found and published with the rule'' or for ''a substantive rule which grants or recognizes an exemption or relieves a restriction.'' [19]

As discussed earlier, DEA, jointly with SAMHSA, is publishing this temporary rule to extend certain exceptions granted to existing DEA regulations in March 2020 as a result of the COVID–19 PHE in order to avoid lapses in care for patients. In particular, if this 30-day delay applied, patients might experience a lapse in care because the existing telemedicine flexibilities would end on May 11, 2023. For these reasons, DEA, jointly with SAMHSA, concludes that such good cause exists to justify an immediate effective date for this temporary rule.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review).

This temporary rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this E.O., as specifically authorized in a timely manner by the Administrator of OIRA in each case.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and DEA has determined that it is a significant regulatory action under E.O. 12866, but not a Section 3(f)(1) significant regulatory action. Accordingly, this rule has been submitted to the OMB for review.

DEA, jointly with SAMHSA, is publishing this temporary rule to extend certain exceptions DEA granted to its existing regulations in March 2020 as a result of the COVID–19 PHE in order to avoid lapses in coverage for patients. DEA and/or SAMHSA anticipate publishing at least one final rule as part of these rulemakings.

Without this temporary rule, COVID–19 PHE telemedicine flexibilities are scheduled to expire on May 11, 2023. This rule extends the expiration of those flexibilities through November 11, 2023 for all telemedicine relationships, and through November 11, 2024, for such telemedicine relationships that were established on or before November 11, 2023. Because this rule does not create or remove any regulatory requirements, DEA and SAMHSA estimate that there is no cost associated with this temporary rule. However, DEA and SAMHSA believe this extension and grace period create a benefit in form of cost savings to prescribers and patients and reduced transfer payments to the federal government, similar to those described in the General Telemedicine Rule.

However, due to the nature of this rule, differing policies between the flexibilities being extended with this temporary rule and the flexibilities still proposed in the General Telemedicine Rule, and the expectation that additional policy will be addressed in a final rule prior to the expiration date of November 11, 2023, DEA is unable to quantify the cost savings and reduction in transfer payments.

Executive Order 12988, Civil Justice Reform

The temporary rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This temporary rule does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This temporary rule does not have substantial direct effects on the Tribes, on the relationship between the national government and the Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this Temporary Rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This Temporary Rule, as discussed above, merely extends for a limited time the status quo with respect to the current flexibilities allowed during the COVID–19 PHE, in order to avoid lapses in coverage for patients.

Without this temporary rule, COVID–19 PHE telemedicine flexibilities would expire on May 11, 2023. While this temporary rule does not create or remove any regulatory requirements, this temporary rule extends the expiration of those flexibilities through November 11, 2023 and provides a grace period for certain telemedicine relationships through November 11, 2024. DEA and SAMHSA believe this extension and grace period create a benefit in form of cost savings to

[18] 5 U.S.C. 553(d).

[19] 5 U.S.C. 553(d)(1), (3).

prescribers and patients and reduced transfer payments to the federal government. However, the benefits have a sunset provision; additionally, this rule is expected to be supplemented by another rule prior to the expiration date of November 11, 2023.

In accordance with the RFA, DEA will be evaluating the impact on small entities at the time the final rule or rules are issued as part of these rulemakings.

Paperwork Reduction Act of 1995

This temporary rule will not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Also, this temporary rule does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or other organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

Congressional Review Act

This temporary rule is not a major rule as defined by Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA).[20] However, pursuant to the CRA, DEA is submitting a copy of this temporary rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1307

Administrative practice and procedure, Drug traffic control, Prescription drugs.

For the reasons set out above, the Drug Enforcement Administration is amending 21 CFR part 1307 as follows:

PART 1307—MISCELLANEOUS

■ 1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Add an undesignated center header after § 1307.31, and add § 1307.41 to read as follows:

Special Exceptions Related to Telemedicine

§ 1307.41 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 November 11, 2024. The authorization granted in paragraph (c) of this section expires at the end of November 11, 2023.

(b) For purposes of this section, a practitioner and a patient have a *telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities* if:

(1) The practitioner has not conducted an in-person medical evaluation of the patient; and

(2) The practitioner has prescribed one or more controlled substances to the patient

(i) Pursuant to the designation on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under 21 U.S.C. 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States for the duration of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247); or

(ii) Pursuant to paragraph (c) of this section.

(c) During the period May 12, 2023 through November 11, 2023, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in § 1300.04(i) of this chapter, to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (e) of this section are met.

(d) During the period November 12, 2023 through November 11, 2024, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in § 1300.04(i) of this chapter, to a patient with whom the practitioner has a telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities without having conducted an in-person medical evaluation of a patient if all of the conditions listed in paragraph (e) of this section are met.

(e) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraphs (c) or (d) 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.

Title 42—Public Health

■ For the reasons set out above, the Department of Health and Human Services adds part 12 to title 42 of the Code of Federal Regulations to read as follows:

PART 12—TELEMEDICINE FLEXIBILITIES

Subpart A—Special Exceptions Related to Telemedicine

Sec.

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

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 November 11, 2024. The authorization granted in paragraph (c) of this section expires at the end of November 11, 2023.

(b) For purposes of this section, a practitioner and a patient have a telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities if:

(1) The practitioner has not conducted an in-person medical evaluation of the patient; and

(2) The practitioner has prescribed one or more controlled substances to the patient

(i) Pursuant to the designation on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under 21 U.S.C. 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States for the duration of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247); or

[20] 5 U.S.C. 804(2).

(ii) Pursuant to paragraph (c) of this section.

(c) During the period May 12, 2023 through November 11, 2023, a 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 (e) of this section are met.

(d) During the period November 12, 2023 through November 11, 2024, a 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 with whom the practitioner has a telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities without having conducted an in-person medical evaluation of a patient if all of the conditions listed in paragraph (e) of this section are met.

(e) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraphs (c) or (d) 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

§ 12.2 [Reserved]

Signing Authority

This document of the Drug Enforcement Administration and the Department of Health and Human Services was signed on May 4, 2023, by Administrator Anne Milgram. Those documents with the original signatures and dates is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

Miriam E. Delphin-Rittmon,

Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2023–09936 Filed 5–9–23; 8:45 am]

BILLING CODE 4410–09–P; 4162–20–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0788; FRL–10880–01–OCSPP]

Cyflufenamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyflufenamid in or on sugar beet. Nippon Soda Co., Ltd. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 10, 2023. Objections and requests for hearings must be received on or before July 10, 2023 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0788 is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0788 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before July 10, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0788, by one of the following methods: