PRESCRIBING CONTROLLED SUBSTANCES USING TELEHEALTH

NATIONAL LAW: The History:

- 2008: **Special registration to prescribe controlled substances through telemedicine** was originally called for in the *Ryan Haight Act of 2008.* The Ryan Haight Act amended the Controlled Substances Act to prohibit the delivery, distribution or dispensing of a controlled substance by "means of the Internet" without first conducting an **in-person exam**. The Act directed the U.S. Drug Enforcement Agency (DEA) to create a **special registration for telemedicine with the goal of increasing patient's access to practitioners who can prescribe controlled substances via telehealth in limited circumstances.** On April 6, 2009, when implementing the Ryan Haight Act (at 74 FR 15603) the DEA stated that the agency would issue a separate rule regarding the special registration for telemedicine. **It has not yet done so.**
- 2018: Congress returned to the issue in the *SUPPORT for Patients and Communities Act*, signed into law on October 24, 2018, which included a provision requiring the Attorney General – in consultation with the Secretary of Health and Human Services – to **within one year** promulgate final regulations related to a Special Registration for Telemedicine.
- 2019: Another deadline was missed when it was not released in October 2019. The Fall 2019 Unified Agenda of Regulatory and Deregulatory Actions announced the Special Registration to Engage in the Practice of Telemedicine **proposed** rulemaking for December 2019.
- About the Regulation: The **anticipated regulation** would enable a practitioner to deliver, distribute, dispense, or prescribe via telemedicine a controlled substance to a patient who **has not been medically examined in-person by the prescribing practitioner**. For example, in the event of an opioid overdose, a patient might need a prescription for an opioid antagonist such as naloxone from a provider who has never examined the patient in-person prior to the telemedicine encounter. The Act also expressly exempts certain practitioners from needing to obtain a special registration for telemedicine in each state where the entities and practitioners choose to practice.
- **Congress did establish three general requirements that practitioners must meet while using the special registration to deliver, distribute, dispense, or prescribe controlled substances via telehealth**:
    - The practitioners must demonstrate a legitimate need for the special registration.
    - The practitioners must be registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located.
    - The practitioners must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance.
- The Alliance for Connected Care convened more than 80 organizations, who jointly signed a letter urging the DEA to move forward with the telemedicine special registration process required by federal law that will enable SAMHSA waivered clinicians, community mental health centers and addiction treatment facilities to prescribe medication assisted treatment (MAT) to patients with Opioid Use Disorder by employing telemedicine technology.
- **As of the writing of this document, the final regulations by the Attorney General in consultation with the Secretary of Health and Human Services has not been established.**
- ***Declaration of the Public Health Emergency (PHE) on Jan 21, 2020, made federal allowances to expanded use of telemedicine in prescribing controlled substances for the duration of the PHE. That will expire at the end of the PHE**.

NATIONAL: FROM DRUG ENFORCEMENT AGENCY (DEA)

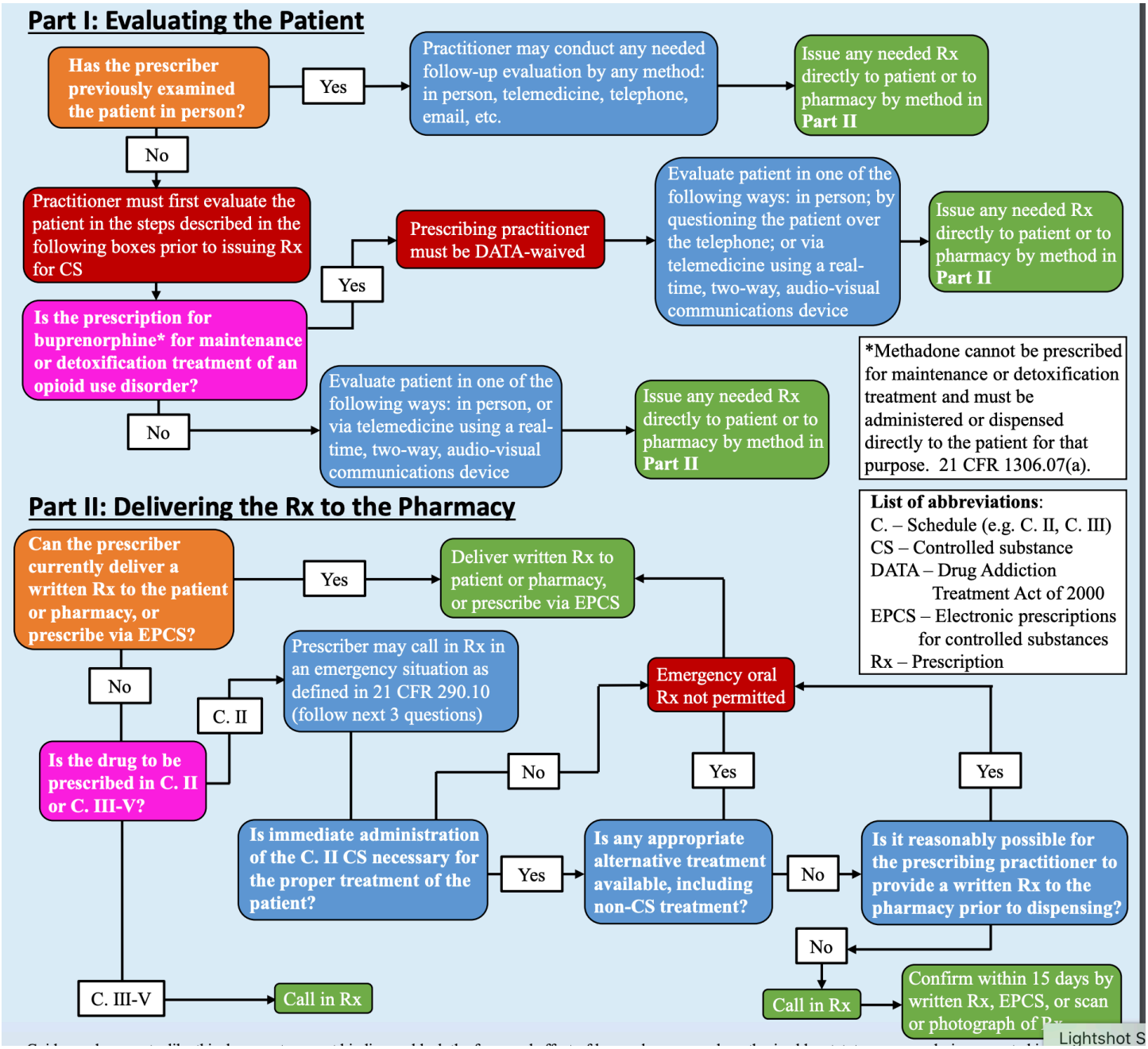
- The declaration of the national emergency enacted one of the exceptions to the Ryan Haight Act for telehealth (telemedicine as it is referred to in the Act).

- **For as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners may issue prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met**:
    - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
    - The telemedicine communication is conducted using an **audio-visual, real-time, two-way interactive communication system.**
    - The practitioner is acting in accordance with applicable Federal and State law.

HOW SHOULD THE PRESCRIPTION BE WRITTEN? Controlled Substances Act and DEA's implementing regulations

- Federal CSA prohibits the refilling of schedule II controlled substances. 21 USC 829(a), 21 CFR 1306.12(a).
- 21 CFR 1306.12(b): "an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance, subject to specific conditions are met. These conditions include, among other things:
    - that the practitioner must sign and date the multiple prescriptions as of the date issued, (21 CFR 1306.05(a));
    - and, write on each separate prescription the earliest date on which the prescription can be filled (21 CFR 1306.12(b)(ii)).
    - A pharmacy filling such prescription has no authority to change this date or dispense the controlled substance to the patient prior to that date.
    - This does not prohibit the practitioner from issuing one prescription for a 90-day supply if allowed by state law and regulation that otherwise comport with 21 CFR 1306.04(a).
- **Emergency Schedule II Prescribing: 21 CFR 1306.11(d).**
    - May be transmitted to the pharmacist ORALLY provided that:
        1. Quantity is limited to what is needed during the emergency
        2. Pharmacist immediately reduces the RX to writing containing all the appropriate details noted in [21 CFR] 1306.05 except for provider signature.
        3. If provider is not known to the pharmacist, pharmacist much attempt to confirm identity of the provider by calling back using a separate method such as calling office listed in phone book.
        4. Within 7 days of issuing the emergency oral prescription, the prescribing provider shall provide a written prescription for the same with "Authorization for Emergency Dispensing" and the date of the oral order. Deliver by mail (postmarked within 7 days of oral rx) or in person. *** **During the PHE, DEA has extended this requirement to 15 days and has allowed the prescription to be scanned or photographed and transmitted by fax to the pharmacy as well.**

DIAGRAM for Controlled Substance Prescribing in Substance Use Disorder and Medical Assisted Therapy Using Telehealth



WV Controlled Substance and Prescribing Laws:

- **Establishing the doctor-patient relationship in WV:**
  - **BEFORE COVID-19 PHE**: Doctor patient relationship must be established according to the rules approved by the appropriate board. WV Code 30-5-4(67). Controlled substances cannot be prescribed without first establishing this relationship. Before COVID 19, this relationship could NOT be done using audio only or text or any combination of these. It COULD be established using interactive AUDIO store and forward or real time video platform visit. Pathologists and radiologists can establish relationship using store and forward telemedicine technology.

- **DURING COVID-19 PHE**: It remains unclear if a NEW patient relationship can be established during COVID with Audio Only, but it is believed to be allowed.
- **AFTER COVID-19 PHE ENDS**:
  - **Established patient** is a patient in the who has been seen in person by the physician or a provider of same specialty in the same group **within the last 3 years.**
  - **Re "Established Patients":** a patient shall visit an (any) in-person provider within 12 months of using the initial telehealth service or the service shall no longer be available to the patient until an in-person visit is obtained. This may be suspended by provider on a case-by-case basis
    - Does not apply to:
      - Acute inpatient care
      - Post-op follow-up
      - Behavioral medicine
      - Addiction medicine
      - Palliative care
  - **To establish a doctor-patient relationship without a face-to face interaction, must use one of the following for the initial visit:**
    - Interactive audio store and forward technology
    - Real time video conferencing
    - For pathology/radiology: store and forward or other similar technologies
    - **Attempt should be made for audio-visual but if not available, audio only call or conversation in real time will suffice**

- **Schedule II-V drugs for non-malignant pain**: WV Code 30-14-12d
  - **BEFORE COVID-19 PHE**: Could NOT prescribe Schedule II-V based SOLELY on a telemedicine encounter. Prohibits providers from issuing prescriptions, electronic or other means, for persons without establishing an ongoing physician-patient relationship, wherein the physician has obtained information adequate to support the prescription. Certain exceptions apply:
    - Documented emergencies
    - On-call or cross coverage situations
    - Where patient care is rendered in consultation with another physician who has an ongoing relationship with the patient; and who has agreed to supervise the patient's treatment, including use of any prescribed medications.
  - Also, if a prescriber practices medicine to a patient SOLELY using telehealth, they may not prescribe any Schedule II substance. Certain exceptions apply:
  - **DURING COVID-19 PHE**:
    - March 31, 2020: Governor Justice waived the requirement of an in-person physical examination every 90 days prior to prescribing a refill for a Schedule II opioid medication to an existing patient for chronic pain treatment (WV cod 16-54-4(h)), provided that the provider utilizes other appropriate tools to evaluate the patient at these intervals and assesses whether continuing the course of treatment would be safe and effective for the patient.
    - WV code 8.9.2 required update before the DEA made their exceptions: They are as follows:
      - 8.9.2: In case of emergency, oral prescription for Schedule II allowed with pharmacist to make effort to confirm identity of provider.
      - 8.9.2.a. Quantity prescribed and dispensed limited to what is needed for the emergency period (DEA admits, no one knows what that quantity should be)

- 8.9.2.b. Provider must provide a follow-up prescription within 15 days: Prescription with wet signature mailed or delivered, sent as fax, sent as photograph, sent as scan

- **AFTER COVID-19 PHE ENDS and as of March 30, 2021 <u>WV HB2024 PASSED</u>**:
  - If physician provides care to a patient solely through telemedicine, Schedule II medications cannot be prescribed. These limitations do not apply to physician or member of the same group practice sharing an established patient.
  - **Prescribing limitations do not apply** when a physician is providing treatment to patients who are minors or if 18 years of age or older, who are enrolled in primary or secondary education and are diagnosed with intellectual or developmental disabilities, neurological disease, Attention Deficit Disorder, Autism or a traumatic brain injury. Must maintain records supporting the diagnosis and continued need for treatment.
  - Physicians cannot prescribe Schedule II substance for chronic pain management based solely on a telemedicine encounter. These limitations do not apply to physician or member of the same group practice sharing an established patient. * It is likely that the 90 day in-office physical examination of patient for pain management will be reinstated when the PHE expires.
  - **SB 714: AFTER THE PHE and as of July 8, 2021: SB 714 PERMANENT: PA-Cs may prescribe three-day supply of Schedule II CS**

- **What about WV APRNs and Schedule II and III**?
  - **BEFORE COVID-19: APRNs were not permitted to prescribe Schedule II.**
  - **DURING COVID-19: April 15, 2020: Governor Justice Executive Order allows Board of Nursing (BON)** at their discretion, to temporarily suspend or modify the requirements for the authorization of prescriptive authority, prescriptive formulary limitations, prescriptive refill and supply limitations, and other prescriptive limitations. BON decided to allow APRNs with current prescriptive authority and an active DEA number, who are approved to practice in WV during the PHE, may REFILL Schedule II drugs of the uniform Controlled Substances Act and Antineoplastics, if the patient has been on these medications. Schedule II prescriptions are permitted to be refilled if the refill is required during the declared emergency. Prescribing physician's name must be written on the prescription along with the last date prescription was filled.
  - APRNs are to contact the DEA office at one of the following numbers: 304-347-5210 or 571-362-5667. Verification will occur. Once everything has been verified, Schedule II authority will be added to the registration. NOTE: Each APRN must call individually. DEA will not add the Schedule II authorization unless APRN calls.
  - **AFTER THE PHE and as of July 8, 2021: SB 714 PERMANENT: APRNs may prescribe three-day supply of Schedule II CS**

- **What about Interstate Telehealth Practitioners registered in WV**?
  - Permanent (WV HB2024) **No Schedule II prescribing** unless allowed in another section of WV Code. Does not apply to provider in the same group as an established patient.
  - **Prescribing limitations do not apply** when a physician is providing treatment to patients who are minors or if 18 years of age or older, who are enrolled in primary or secondary education and are diagnosed with intellectual or developmental disabilities, neurological disease, Attention Deficit Disorder, Autism or a traumatic brain injury. Must maintain records supporting the diagnosis and continued need for treatment.