Summary of Federal Prescribing Regulations

Federal Regulations for Prescribing Controlled Substances (CS)
The Controlled Substances Act (CSA) of 1970 regulates the manufacturing, distribution, prescribing, and dispensing of drugs with the potential for abuse or physical or psychological dependency.\(^1\) The central goals of the CSA are to prevent abuse, trafficking and diversion of controlled substances, while ensuring that medications are accessible to all patients who need them for pain relief.
Summary of Federal Prescribing Regulations

Controlled Substances Act (CSA)

- Health care professionals are required to comply with both federal and state regulations that govern prescribing a scheduled controlled substance\(^1\)
- In event of conflicting regulations, the more stringent regulation applies\(^2\)

\(^1\)Federation of State Medical Boards. Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. May 2004.

Healthcare professionals are required to comply with state and federal regulations for controlled substances. Healthcare professionals should follow the most stringent regulations.
Summary of Federal Prescribing Regulations

Federal Guidelines for Opioid Prescribing

Title 21 Code of Federal Regulations (21 CFR 1300) published by the US Drug Enforcement Administration (DEA)

• The CFR defines
  – How opioids are to be prescribed
    ▪ By prescribing physician
    ▪ To patient receiving treatment
  – Roles and responsibilities of health care professionals involved

The federal guidelines for opioid prescribing are clearly defined in Title 21 of the Code of Federal Regulations, part 1300 and are published by the US Drug Enforcement Administration. These regulations control how opioids are prescribed and dispensed. The regulations also identify the roles and responsibilities of prescribing and dispensing healthcare professionals.

You can find a web site address and a link to the official DEA web site in the Resource Center of the Emerging Solutions in Pain Tool Kit.
Summary of Federal Prescribing Regulations

Key Aspects of CFR

• Prescribing of controlled substances (part 1306)
  – The purpose of issuance
  – The manner of prescribing
  – Prescription requirements
  – Prescription dispensing
• Schedules of controlled substances (part 1308)
• Records and reports (part 1310)
• Administrative functions, practices and procedures (part 1316)

Key aspects of the CFR focus on prescribing of controlled substances, with required information that includes the purpose of issuance and the manner of prescribing. Also included in this section, are prescription requirements and guidelines for prescription dispensing. Other areas of the code provide information on schedules of controlled substances, as well as additional requirements for maintaining records and reports, and administrative functions, practices and procedures.
Federal law clearly states that a schedule II medication can be administered, prescribed, or dispensed to a person with intractable pain in which no relief or cure is possible, or none has been found after with reasonable effort. Appropriately, this is the definition of a chronic pain patient.

Furthermore, part 1306.07 of the CFR notes that the prescribing, dispensing, or administration of a narcotic medication to a narcotic-addicted patient for the purpose of alleviating pain is not restricted, but such prescribing must be medically appropriate within the standards set by the medical community.

This regulation was set forth in order to clarify that a practitioner may treat pain with schedule II medications in addicted individuals, but cannot use schedule II medications to treat, maintain or detoxify an individual with the disease of addiction. A separate registration with the Attorney General’s office is required in order to provide maintenance treatment and detoxification to patients with the disease of addiction. This registration must be renewed annually.
The responsibility for proper prescribing and dispensing is equally shared by the prescribing physician and the dispensing pharmacist. Physicians must write prescriptions in accordance with the regulations. Pharmacists must comply with the regulations regarding dispensing of controlled substances. Improper prescribing and/or dispensing practices can lead to action by regulatory authorities.
Prescriptions for controlled substances must be issued for a legitimate medical purpose in the usual course of professional practice. Prescriptions must be written in accordance with an appropriate consultation. For example, controlled substances for pain must be prescribed when a patient is consulting their physician for treatment of their pain. Requests for treatment for pain outside a pain consultant should be referred as appropriate.
All prescriptions for controlled substances must also be provided in their original written form and include:
- the date and physician’s signature on the actual date the prescription was written;
- the patient’s full name and address;
- the drug name, dose, dosage formulations and quantity prescribed;
- directions for use; and
- the prescribing physician’s name, address, and registration number.

While prescriptions for schedule II controlled substances may, under certain circumstances, be faxed to the pharmacy, the original written prescription must be presented to the pharmacist for review before it can be dispensed.
Summary of Federal Prescribing Regulations

Emergency Exceptions:
21 CFR 1306.11

- Pharmacist may accept verbal authorizations and dispense medication, provided
  - Quantity prescribed and dispensed is limited to what is needed for the emergency period
  - Dispensing pharmacist immediately transcribes the verbal order containing all information except the physician’s signature
  - Dispensing pharmacist confirms that verbal authorization was originated by a registered physician
  - Physician presents an original written prescription within 7 days of the emergency verbal prescription

The only exception to this requirement is in an emergency situation, in which a pharmacist may accept verbal authorization of prescriptions for schedule 2 controlled substances. However:

- The quantity prescribed and dispensed must be limited to the amount needed for the emergency period only
- The dispensing pharmacist must immediately transcribe the verbal order into a written prescription containing all the necessary information except the physician’s signature
- The dispensing pharmacist must make a reasonable effort to confirm that the verbal authorization was originated by a registered physician, if the prescribing physician is not known to the pharmacist; and
- The physician must present an original written prescription for the emergency prescription to the pharmacist within 7 days of authorizing the emergency prescription

Summary of Federal Prescribing Regulations

Limitations of the CSA

- The CSA has contributed to the undertreatment of pain
  - Access to controlled prescription medications
  - Physician prescribing practices


Sometimes referred to as “the chilling effect”, the Controlled Substances Act has contributed to the undertreatment of pain, both by limiting access to controlled prescription medications such as opioids and by inhibiting physician prescribing practices.
Summary of Federal Prescribing Regulations

Just as improper prescribing of controlled substances is a federal offense under the CSA, proper prescribing is mandated by the Pain Relief Act, which protects physicians who engage in justifiable pain management practices. It’s all about balance. By becoming familiar with federal and state regulations and consistently documenting the prescribing of controlled medications, physicians can optimize pain management while reducing regulatory scrutiny.

Summary of Federal Prescribing Regulations

**Summary**

- Federal and state regulations aim to ensure appropriate prescribing of controlled substances for pain relief in all patients.
- In order to reduce regulatory scrutiny, physicians should:
  - Consistently document the prescription of all controlled substances.
  - Work cooperatively with dispensing pharmacists.

In summary, the federal regulations concerning controlled substances are designed to ensure appropriate prescribing for pain relief in patients requiring opioid therapy. These may be made more stringent by additional state regulations. Regulatory intervention may be reduced by consistently documenting the prescription of all controlled substances, ensuring such prescriptions are properly written, and working cooperatively with dispensing pharmacists.