Review of Pharmacy Examining Board Phar 8

https://docs.legis.wisconsin.gov/code/admin_code/phar/8

and

Federal 2020 DOJ/DEA Pharmacy Manual guidance

https://www.deadiversion.usdoj.gov/pubs/manuals /

1/28/2021

Some Differences between State and Federal

1. *Record Retention*: State 5 year, Fed 2 year
2. State Prescription *Renewal* vs. **Federal** *Refill*: Different terms to mean same thing.
3. *Physical inventory* every 2 years. Rules Committee indicated it may prefer annual. Authority?
4. *Schedule V, terms*: state, register vs. **Fed** logbook.
5. *Recordkeeping*: Wisconsin – to DEA and Pharmacy Board within 2 weeks of filing to DEA. **Fed** – Report to DEA and complete form 106 found online. Within one day.
6. *Dispensing controlled substances* without a prescription: much more specific in **federal**
7. *Reporting theft or loss*: Wisconsin – to DEA and Pharmacy Board within 2 weeks of filing to DEA. **Fed** – Report to DEA and complete form 106 found online. Within one day.
8. Federal outlines specifics for *direct dispensing*. Phar 8 does not.
9. Wisconsin –Discusses term *"emergency"*. Requires notification to Pharmacy Board if no written prescription. **Fed** – Discusses term "emergency situation." Pharmacist to notify DEA as a requirement, not included in state requirements.
10. *Label requirements*: Wisconsin –requirements same as federal; No Central fill requirements, No Caution phrase requirement. Fed- requirements for Central fill pharmacies. Includes Caution phrase, not required under Phar 8
11. **Feds** permit 90-day supply with conditions. State does not indicate in Phar 8.

Issue	Phar 8	Federal	Comparison
Recordkeeping – Inventory, record retention	Phar 8.02 (2) 5-year record retention policy	If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically. 21 CFR 1311.305(a). Electronic records must be maintained electronically for two years from the date of their creation or receipt. 21 CFR 1311.305(b). Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read. 21 CFR 1311.305(c).	Wis – 5 year Fed – 2 year States are authorized to have longer record retention policy.
Recordkeeping – Inventory	Phar 8.02(2) A complete and accurate **biennial physical inventory** of all schedule II, III, IV and V controlled substances pursuant to s. 961.16, 961.18, 961.20 and 961.22, Stats., and ch. CSB 2 on hand shall be made in conformance with all applicable federal and state laws.	After the initial inventory, the registrant is required to take a new inventory **at least every two years**, which requires the same information as the initial inventory of all controlled substances on hand. 21 CFR 1304.11(c). There is no requirement to submit a copy of the inventory to DEA. Under 21 CFR 1304.11(a), (b) and (e)(6), the inventory shall include: 1. The date of the inventory, 2. Whether the inventory was taken at the beginning or close of business, 3. The name of each controlled substance inventoried, 4. The finished form of each of the substances (e.g., 10 milligram tablet), 5. The number of dosage units or volume of each finished form in the commercial container (e.g., 100 tablet bottle or 3 milliliter vial),	Same Wis and Fed - 2 year physical inventory

		6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and 7. The total count of the substance.	
Issue	**Phar 8**	**Federal**	**Comparison**
Recordkeeping – Inventory, identification card	s. 450.11 (1b)(bm), Stats. A pharmacist or other person dispensing or delivering a drug shall legibly record the name on each identification card presented under par (b) to the pharmacist or other person, and the name of each person to whom a drug is dispensed or delivered subject to par (e)2., and shall maintain that record for a time established by the board by rule or, for a record that is subject to s. 961.385, until the name is delivered to the controlled substances board under s. 961.385, whichever is sooner. Phar 8.02 (3) (d) Any person authorized to manufacture, distribute or dispense controlled substances shall maintain complete and accurate records with the following information: **1.** The name of the substance. **2.** The dosage form, strength and quantity of the substance. **3.** The quantity and date of distribution as well as the name, address and DEA registration number of the person to whom distributed. **4.** The number of units and date of receipt as well as the name, address and DEA registration number of the person from whom received. **5.** The name and address of the person for whom dispensed, date of dispensing, quantity dispensed and name or initials of the individual who dispensed the substance.	The CMEA requires an individual to present an unexpired identification card that includes a photograph and is issued by a state or the Federal Government or a document considered acceptable under 8 CFR 274a.2(b)(1)(v)(A) and (B). Pursuant to 21 CFR 1304, the records which must be maintained by a pharmacy are: Executed official order forms (DEA Form 222) or the electronic equivalent. Power of Attorney authorization to sign order forms. 21 CFR 1305.05(a). Receipts and/or invoices for schedules III, IV, and V controlled substances. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors Records of controlled substances dispensed, to include prescriptions or a logbook of controlled substances which may be lawfully dispensed without a prescription. **Schedule III-IV.** The electronic system must provide online retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information	Wis – requires reporting of name to CSB. List of required data Fed – lists required data virtually same as state however refills are permitted

		must include, but is not limited to: the original prescription number; date of issuance; full name and address of the patient; the prescriber's name, address, and DEA registration number; the name, drug strength, dosage form and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescriber. 21 CFR 1306.22(f)(1).	
Issue	**Phar 8**	**Federal**	**Comparison**
Recordkeeping – Inventory Schedule II, III, IV, V	Phar 8.02 (3) Required records shall be maintained as follows: (a) Records of schedule II controlled substances, other than prescription orders, shall be maintained separately from all other records. (b) Records of schedule III, IV and V controlled substances shall be maintained either separately or in such form that the information required is readily retrievable from the registrant's ordinary records. (c) The official drug enforcement administration order forms, DEA form 222, used in the procurement and distribution of schedule II substances shall be maintained at the locations from which the drug was distributed and where it is received.	Separate filing for schedule II. Prescriptions for schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for schedules III, IV, and V, or in such form that they are readily retrievable from the other prescription records of the pharmacy. 21 CFR 1304.04(h)(4). Required submission of DEA form 222 for Schedule II drug orders. Readily retrievable invoices for schedule III, IV, V. A pharmacy's electronic system must have the capability of printing out any refill data which the pharmacy must maintain under the CSA. a. Prescribing practitioner's name b. Patient's name and address c. Quantity and date dispensed on each refill d. Name or identification code of the dispensing pharmacist e. Original prescription number	Virtually the same provisions.

		In any electronic system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours. 21 CFR 1306.22(f)(4).	
Recordkeeping - Schedule V	Phar 8.02 (3) (e) Records for dispensed schedule V substances shall be maintained as follows: 1. If a schedule V drug is dispensed pursuant to the prescription order of a practitioner, the prescription shall be labeled properly and the order filed in accordance with the requirements for schedule III and IV orders. 2. If a schedule V drug is dispensed other than pursuant to a prescription order, the dispenser shall make the record required by s. 961.23, Stats., in a bound controlled substance V register at the time of the transaction.	Records of controlled substances dispensed, to include prescriptions or a logbook of controlled substances which may be lawfully dispensed without a prescription.	State – Outlined in statutes in s. 961.23 "record required in a bound controlled subs V register. Fed - logbook

Recordkeeping – Theft or loss reporting to DEA and board	Phar 8.02 (f) In any instance that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner or other DEA registrant shall also send a copy to the board within 2 weeks of filing with the DEA.	Under 21 CFR 1301.76(b), should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss. A. Notify DEA and Local Police The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of a controlled substance. 21 CFR 1301.76(b). Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. DEA must be notified directly. 21 CFR 1301.76(b). This requirement is not satisfied by reporting the theft or significant loss in any other manner. A pharmacy must complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) (21 CFR 1301.76(b))	Wisconsin – to DEA and Pharmacy Board within 2 weeks of filing to DEA. Fed – Report to DEA and complete form 106 found online. Within one day.
Filling Orders – Recordkeeping	Phar 8.03 (1) All controlled substance prescription orders shall be maintained on file, in chronological order, for a period of at least 5 years. The orders shall be readily accessible to enforcement personnel authorized by s. 961.51, Stats.	Electronic records must be maintained electronically for two years from the date of their creation or receipt. 21 CFR 1311.305(b). Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read. 21 CFR 1311.305(c).	State – five years Fed – two years

Issue	Phar 8	Federal	Comparison
Filling Orders – Schedule II	Phar 8.03 (2) Schedule II prescription orders may be filed separately from all other orders or they may be filed with those for schedule III, IV and V drugs provided all orders in the file for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height, in the lower right hand corner of the order. Under no circumstances may schedule II orders be filed together with those for non-controlled drugs. Phar 8.05(4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written hard copy or electronic order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order	Only schedule I and II controlled substances are ordered with an official paper order form, DEA Form 222, or the electronic equivalent (See below, Controlled Substance Ordering System (CSOS) – Electronic Order Forms.) DEA Forms 222 must be maintained separately from all other records of the registrant. 21 CFR 1305.17(c). DEA Forms 222 are required to be kept available for inspection for a period of two years. 21 CFR 1305.17(c). Paper prescriptions for schedule II controlled substances shall be maintained at the registered location in a separate prescription file. 21 CFR Part 1306 - the pharmacist is to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files.	Virtually the same Specifically noted a "C" for state Feds are "make notation"
Filling Orders - Identification of III, IV and V orders – hard copy vs electronic	Phar 8.03 (3) Schedule III, IV and V prescription orders may be filed with those for non-controlled drugs provided that orders for schedule III, IV and V drugs are stamped in red ink with the letter "C" one inch in height in the lower right hand corner of the order or orders for schedule III, IV and V substances may be filed separately. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescription orders which permits identification by prescription order number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription order with a red ``C" is waived.	21 CFR 1304.04(h)(2). Prescriptions for schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for schedules III, IV, and V, or in such form that they are readily retrievable from the other prescription records of the pharmacy. 21 CFR 1304.04(h)(4). 21 CFR Part 1306 - the pharmacist is to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files.	Waiver of "C" if digital system is used.

Purpose of Order Legitimate medical purpose and corresponding responsibility.	Phar 8.04 (1) Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.	An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of 21 U.S.C. 829. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). A pharmacist has a corresponding responsibility for the proper dispensing of controlled substances. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 U.S.C. 841(a)(1), 21 U.S.C. 842(a)(1), and 21 CFR 1306.04(a).	Virtually same provision
Issue	**Phar 8**	**Federal**	**Comparison**
Dispensing Requirements of prescription orders (info on written orders) Issuance by authorized practitioners-registered or exempted under	Phar 8.05 (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. Orders for	A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. 21 CFR 1306.05(a). Under 21 CFR 1306.05(a), 1306.22(b), the prescription must also include: Drug name, Drug strength, Dosage form, Quantity	Federal includes number of refills authorized, to be included on the prescription.

federal controlled substance act.	controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.	prescribed, Directions for use, Number of refills authorized (if any) A paper prescription must be written in ink or indelible pencil or typewritten, or printed on a computer printer, and must be manually signed by the practitioner on the date when issued.	
Dispensing Schedule II, III, IV dispensing, dating, personal knowledge of person for schedule II, no personal knowledge then name/address and signature of person on back.	Phar 8.05 (2) A pharmacist may dispense a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, specified in s. 961.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.	The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription as required by law. 21 CFR 1306.14(a), 1306.24(a).	Differences noted.
Dispensing Schedule II, III, IV dispensing- labels, records	Phar 8.05 (3) An individual practitioner may dispense directly a controlled substance listed in schedule II, III or IV provided that the prescription container is labeled and records are maintained in accordance with the requirements of this code.	Dispensing a controlled substance without a prescription is governed by 21 CFR 1306.26. The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that: 1. Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist 21 CFR 1306.26(a). 2. Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other	Specifics of criteria for direct dispensing are outlined in federal.

		such controlled substance, may be dispensed at retail to the same purchaser in any given 48-hour period. 21 CFR 1306.26(b). 3. The purchaser is at least 18 years of age. 21 CFR 1306.26(c). 4. The pharmacist requires every purchaser of a controlled substance not known to him to furnish suitable identification (including proof of age where appropriate). 21 CFR 1306.26(d). 5. A bound record book must be maintained in accordance with the recordkeeping requirement of 21 CFR 1304.04. (See Section VI – Recordkeeping Requirements.) It is maintained by the pharmacist, and contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser. 21 CFR 1306.26(e). 6. A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law. 21 CFR 1306.26(f).	
Dispensing Schedule II dispensing, 60 day limit	Phar 8.05 (4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written hard copy or electronic order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.	Schedule II controlled substances require a written prescription which must be manually signed by the practitioner or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances. 21 CFR 1306.11(a), 1306.08, 1311.100(b). There is no federal time limit within which a schedule II prescription must be filled after being signed by the practitioner. However, the pharmacist must determine that the prescription is still needed by the patient, and the amount dispensed must be consistent with the requirement that a prescription for a	State- 60 day time limit for dispensing Federal – no time limit, LTCF does have 60 day limit for Schedule II prescriptions.

		controlled substance be issued only for a legitimate medical purpose. 21 CFR 1306.04(a). For a schedule II controlled substance, an oral order is only permitted in an emergency situation. 21 CFR 1306.11(d).	
Issue	**Phar 8**	**Federal**	**Comparison**
Dispensing Required info, allowable modifications. Changes with consultation	Phar 8.05 (7) A prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substance prescription order, a pharmacist may not add, modify or clarify the patient's name, the controlled substance prescribed, except for generic substitution as permitted by law, and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify or clarify any information allowed in this subsection missing from a prescription order for a schedule III, IV or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient's address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition,	A pharmacist may dispense a schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except in an emergency situation as defined in the FDA regulations, and as described below. 21 CFR 1306.11(a).	Wisconsin - allows consultation for schedule II to change the prescription. See green. Fed – it is not clear that this is allowable. Word 'consultation' is not found in manual.

	modification or clarification of information and the manner by which the pharmacist obtained that information.		
Issue	**Phar 8**	**Federal**	**Comparison**
Dispensing – practitioners of a hospital or institution	N/A	21 CFR 1301.22(c), practitioners who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that: 1. The dispensing, administering, or prescribing is in the usual course of professional practice. 2. The practitioner is authorized to do so by the state in which he or she is practicing. 3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state. 4. The practitioner acts only within the scope of employment in the hospital or institution. 5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.	State does not include requirements for agents or employees of a hospital related to registration at DEA.
Renewals	Phar 8.06 (1) No prescription containing a schedule II substance may be renewed. (2) The prescribing practitioner may authorize renewals of schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization transmitted to the pharmacist. The following conditions must be met:	The refilling of a prescription for a controlled substance listed in schedule II is prohibited. 21 U.S.C. 829(a). Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled	Virtually Same Provisions on "Renewals" or "Refills" Wisconsin uses term renewal, renewed, etc. Fed uses term refill, refilling, refilled.

	(a) The pharmacist obtaining the electronic or oral authorization shall note on the prescription order, medication profile record or readily retrievable and uniformly maintained document the following information: 1. Date authorization is received. 2. Quantity of drug authorized. 3. Number of renewals. 4. Identification of practitioner authorizing the renewals if different from the original prescriber. 5. Identification of the pharmacist who received the authorization. (b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription. **(3)** No prescription containing a controlled substance listed in schedule III or IV may be dispensed or renewed more than 6 months after the date on which the prescription order was issued and no prescription authorized to be renewed may be renewed more than 5 times. **(4)** A prescription containing a drug listed in schedule V may be renewed only as expressly authorized by the practitioner.	up to five times within six months after the date of issue. Schedule V Refills as authorized when prescription is issued or if renewed by a practitioner	
Issue	**Phar 8**	**Federal**	**Comparison**
Partial Dispensing	Phar 8.07 (1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V. **(2)** The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written hard copy prescription order or written record of the electronic or emergency oral prescription order. The remaining portion of the prescription may be dispensed within 72	A prescription for a schedule II controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further	Virtually the Same Wisconsin – prescription order Federal – prescription. An order implies the ordering of Controlled substances schedule I or II that requires DEA form 222 be filled out for the order.

	hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.	quantity may be supplied beyond 72 hours without a new prescription. 21 CFR 1306.13(a).	
Partial Dispensing – LTCF/Terminal illness	Phar 8.07(3) Prescription orders for schedule II-controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase "terminal illness" or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is "terminally ill" or an "LTCF patient." A prescription order that is partially dispensed and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable, the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing	A prescription for a schedule II controlled substance written for a patient in an LTCF or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. 21 CFR 1306.13(b). If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. 21 CFR 1306.13(b). Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. 21 CFR 1306.13(b). The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." 21 CFR 1306.13(b). A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. 21 CFR 1306.13(b). For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. 21 CFR 1306.13(b). The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. 21 CFR 1306.13(b). Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not	Section is substantially the same between Wisconsin and Federal. Issues: No longer required to have medication profile record from previous Phar 7.07. – now medication profile record system under Phar 7.11(3) Notation is required under fed CSA, not clear what violations exist from Wisconsin. Prescription order vs. Prescription

	pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.	to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. 21 CFR 1306.13(b).	
Issue	**Phar 8**	**Federal**	**Comparison**
Partial Dispensing Schedule II LTCF/terminal illness, computerized system and retrieval of information.	Phar 8.07 (4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit: (a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3). (b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription. (c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.	Not identified in federal specific to LTCF– application to general electronic filing for recordkeeping applies. General provisions for types of drugs applies.	Wisconsin/federal provisions provide the same intent, as all prescriptions require recordkeeping. The difference is identification of terminal illness. Medication profile system outlined in Phar 7.11(3).

Issue	Phar 8	Federal	Comparison
Labeling prescriptions	Phar 8.08 Labeling prescriptions. (1) The pharmacist dispensing a prescription containing a controlled substance shall affix to the immediate container a label showing the date of dispensing; the pharmacy name and address; serial number of the prescription; full name of the patient; name of the prescribing practitioner; directions for use; and cautionary statements, contained in the prescription order or required by law. (2) Practitioners who personally dispense any controlled substance to patients in the course of their professional practice other than by prescribing or administering shall conform to ch. Med 17, standards for dispensing drugs.	The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription as required by law. 21 CFR 1306.14(a), 1306.24(a). In addition to this information, if a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy. 21 CFR 1306.14(b), 1306.24(b). Federal Food and Drug Administration (FDA) regulations found in 21 CFR 290.5 require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. 21 U.S.C. 802(10) and (27).	Wisconsin – label requirements same as federal No Central fill requirements No Caution phrase requirement Federal – laws for Central fill pharmacies. Includes Caution phrase, not required under Phar 8
Emergency Dispensing	Phar 8.09 Emergency dispensing. (1) For the purpose of authorizing an oral prescription order for a schedule II controlled substance, the term "emergency" means those situations in which the prescribing practitioner determines that:	Under FDA and DEA regulations, an "emergency situation" in this context means that the prescribing practitioner has determined that immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no appropriate alternative	Wisconsin –Discusses term "emergency". Requires notification to Pharmacy Board if no written prescription.

	Phar 8.09(1)(a) (a) Immediate administration of the controlled substance is necessary for proper treatment of the patient. (b) No appropriate alternative treatment is available, including the administration of a drug which is not a schedule II controlled substance. (c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing. (2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a practitioner if: (a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. (b) The prescription order is immediately reduced to writing by the pharmacist and contains all information required in s. Phar 8.05, except for the signature of the practitioner. (3) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using good faith efforts to insure the practitioner's identity. (4) Within 7 days after authorizing an emergency oral prescription order, the practitioner shall cause a written or electronic order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face "authorization for emergency dispensing" and the date of the oral order. The written or electronic order may be delivered to the pharmacist in person or by mail or electronically, but if delivered by mail it shall be postmarked within the 7 day period. Upon receipt, the	treatment is available (including a drug which is not a schedule II controlled substance), and it is not reasonably possible for the prescribing practitioner to provide a written prescription for the drug at that time. 21 CFR 1306.11(d) and 21 CFR 290.10. A practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. Under 21 CFR 1306.11(d), the prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements: 1.The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner. 21 CFR 1306.11(d)(1). 2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all required information, except for the prescribing practitioner's signature. 21 CFR 1306.11(d)(2). 3. If the prescribing individual practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity. 21 CFR 1306.11(d)(3). 4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the emergency	Fed – Discusses term "emergency situation." Pharmacist to notify DEA as a requirement, not included in state requirements. These not consistent. Fed - Electronic Prescription requirements Wisconsin – No requirements on electronic prescriptions (Phar 8.)

	dispensing pharmacist shall attach this prescription order to the oral emergency order reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of safety and professional services if the practitioner fails to deliver the written or electronic order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written or electronic order of a practitioner.	quantity of the controlled substance prescribed. 21 CFR 1306.11(d)(4). The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. 21 CFR 1306.11(d)(4). The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. 21 CFR 1306.11(d)(4). 5. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. 21 CFR 1306.11(d)(4). 6. By regulation, the pharmacist must notify the local DEA Diversion Field Office (Appendix K) if the prescriber fails to provide a written prescription within seven days. 21 CFR 1306.11(d)(4). Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner. 7. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. 21 CFR 1306.11(d)(4).	
Suspicious orders – Disclosure to DEA	Phar 8.10 Disclosure of suspicious orders of controlled substances. Manufacturers and distributors of controlled substances shall disclose suspicious orders of controlled substances. Suspicious orders include, without limitation because of enumeration, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. The licensee shall notify the regional office of the DEA and the board of all suspicious orders.	…pharmacies must have a system to identify any suspicious orders, which when identified must be reported online to SORS. The Suspicious Orders Report System (SORS) should be accessed on-line and only be used by DEA registrants that distribute controlled substances to other DEA registrants. Reporting a suspicious order to SORS Online constitutes compliance with the reporting requirement under 21 U.S.C. 832. The SUPPORT Act requires that ALL DEA registrants that distribute	Wis – Notify regional office of DEA. Pharmacy Board. Fed – Notify online to SORS Differences noted.

		controlled substances report suspicious orders to DEA.	
Issue	**Phar 8**	**Federal**	**Comparison**
LTCF Emergency Kits	Phar 8.11 Controlled substances in emergency kits for long term care facilities. Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances: (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner. (2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit. (3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories. (4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.	…an emergency kit is for use in emergencies as defined by the state… in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription or medical order. 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a), 21 CFR 1300.01(b) ("prescriptions"). Thus, where the kit is maintained at the LTCF by a pharmacy, controlled substances may not be dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of 21 CFR 1306.11, 1306.21. No changes since 1980 on these fed provisions.	State and Federal generally have similar provisions. Wisconsin – What is a pharmaceutical services committee and where is it defined? Federal – No such committee. State - Monthly inventory required Fed – periodic inventory required.

	(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.		
Issue	**Phar 8**	**Federal**	**Comparison**
Prescription Orders by Fax machine Schedule II and others	Phar 8.12 Prescription orders transmitted by facsimile machine. Phar 8.12(1)(1) Prescription drugs other than schedule II controlled substances. A pharmacist may dispense a prescription drug, other than a schedule II controlled substance, pursuant to a prescription order transmitted by a facsimile machine from the practitioner or the practitioner's agent to the dispensing pharmacy if all of the following conditions are met: (a) The transmitted facsimile prescription order shall contain all of the information required for a valid written prescription order. The order shall also contain the time and date of the transmission, as well as the telephone number and name of the transmitter. (b) Unless the facsimile paper is non-fading, the facsimile prescription order received shall be duplicated by copy machine or other similar device and the copy must be physically attached to the order received. (2) Schedule II controlled substances. A pharmacist may not dispense a schedule II controlled substance pursuant to a prescription order transmitted by a facsimile machine unless all of the conditions stated in sub. (1) are satisfied, and any of the following conditions are met: (a) The prescription order is written for a schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, and is transmitted by the practitioner or	The original schedule II prescription must be presented to the pharmacist and verified against the facsimile prior to the actual dispensing of the controlled substance. 21 CFR 1306.11(a). The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept. 21 CFR 1306.11(a), 1304.04(h). Three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription if: 1. A practitioner prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The facsimile serves as the original written prescription and no further documentation is required. All normal requirements of a legal prescription must be followed. 21 CFR 1306.11(e). 2. Practitioners prescribing schedule II controlled substances for residents of Long-Term Care Facilities may transmit, or direct their authorized agent to transmit, a prescription to the dispensing pharmacy by facsimile. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required. 21 CFR 1306.11(f).	

	the practitioner's agent to the dispensing pharmacy by facsimile. (b) The prescription order is written for a schedule II controlled substance for a patient who resides in a long term care facility, or who meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. (c) The prescription order is written for a schedule II controlled substance for a patient enrolled in a hospice certified by medicare under Title XVIII or licensed by this state, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. (3) Prescription orders transmitted by facsimile considered written orders. For all purposes under chs. 450 and 961, Stats., and the rules of the board, a prescription order transmitted by facsimile machine shall be considered the original written prescription order.	3. A practitioner prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state, may transmit, or direct his or her authorized agent to transmit, a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required. 21 CFR 1306.11(g). A pharmacist may dispense directly a controlled substance listed in schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or a call-in prescription which is promptly reduced to writing by the pharmacist. 21 CFR 1306.21(a).	
ID Card Exception for Health Care Facility	Phar 8.13 Identification card exception for a health care facility. In s. 450.11 (1b) (e) 3., Stats., "health care facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.	N/A	State ID requirement for health facilities is an exception noted.

90 Day Supply-multiple prescriptions for schedule II drugs	N/A	Under 21 CFR 1306.12(b)(1), 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 provided the following conditions are met: 1. Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.12(b)(1)(i). 2. The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription. 21 CFR 1306.12(b)(1)(ii). 3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse. 21 CFR 1306.12(b)(1)(iii). 4. The issuance of multiple prescriptions is permissible under applicable state laws. 21 CFR 1306.12(b)(1)(iv). 5. The individual practitioner complies fully with all other applicable requirements under the CSA and CFR, as well as any additional requirements under state law. 21 CFR 1306.12(b)(1)(v).	Feds permit 90 day supply with conditions.

Summary of Controlled Substances Act Requirements

	Schedule II	Schedules III & IV	Schedule V
Registration	Required	Required	Required
Receiving Records	DEA Form 222	Invoices, readily retrievable	Invoices, readily retrievable
Prescriptions	Written[1] prescriptions (oral prescriptions only allowed in emergency situations)[2]	Written, oral, or fax	Written, oral, or fax
Refills	No	No more than 5 within 6 months	As authorized when prescription is issued or if renewed by a practitioner
Maintenance of Prescriptions[3]	Separate file	Separate file or readily retrievable	Separate file or readily retrievable
Distribution Between Registrants	DEA Form 222	Invoices	Invoices
Security	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals
Theft or Significant Loss	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106

NOTE: ***All records*** must be maintained for 2 years, unless state law requires a longer period. 21 U.S.C. 827(b).

[1] Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.

[2] Emergency oral prescriptions are allowable under schedule II and require a signed follow-up prescription within seven days. 21 CFR 1306.11(d)(4). Exceptions: A facsimile prescription for a schedule II controlled substance serves as the original prescription when issued to a resident of an LTCF. 21 CFR 1306.11(f). A facsimile prescription for a schedule II narcotic substance serves as the original prescription when issued to hospice patients, or patients with a diagnosed terminal illness, or for direct administration by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion. 21 CFR 1306.11(e), (f) and (g).

[3] The record of dispensing can also be a bound record book, if the controlled substance is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act. 21 CFR 1306.26(e). 2020