Chapter CSB 4

PRESCRIPTION DRUG MONITORING PROGRAM

Note: Chapter Phar 18 was renumbered chapter CSB 4 under s. 13.92 (4) (b) 1., Stats., Register September 2015 No. 717.

CSB 4.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 227.11 (2) (a) and 961.385, Stats., for the purpose of creating a prescription drug monitoring program to collect and disclose information relating to the prescribing and dispensing of monitored prescription drugs.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4–1–17; CR 17–028: am. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.02 Definitions. As used in this chapter:

(1) "Access" means to have the ability to view monitored prescription drug history reports, audit trails, and PDMP data as authorized by s. CSB 4.09.

(2) "Administer" has the meaning given in s. 961.385 (1) (a), Stats.

(2m) "Agent" has the meaning given in s. 961.385 (1) (ab), Stats.

(3) "Animal" has the meaning given in s. 89.02 (1m), Stats.

(3m) "ASAP" means the American Society for Automation in Pharmacy.

Note: Contact: American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160; Blue Bell, PA 19422; phone: (610) 825–7783; fax: (610) 825–7641; webpage: http://asapnet.org/index.html.

(3s) "Audit trail" means the log that contains information about each time the PDMP system discloses PDMP data, monitored prescription drug history reports, and prescribing metrics reports.

(4) "Board" means the Controlled Substances Board.

(4m) "Business day" has the meaning given in s. 961.385 (1) (ad), Stats.

(5) "Controlled substance" means a drug, substance, analog, or precursor described in any of the following:

(a) Schedule I, II, III, IV, or V in the federal controlled substances act, 21 USC 812 (b) (1) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV, or V in subch. II of ch. 961, Stats., as amended by ch. CSB 2.

(5m) "Deliver" or "delivery" has the meaning in s. 961.385 (1) (ae), Stats.

(6) "Department" means the department of safety and professional services.

(7) "Dispense" has the meaning given in s. 961.385 (1) (af), Stats.

(8) "Dispenser" means all of the following:

(a) A pharmacy.

Note: A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) A practitioner who dispenses a monitored prescription drug.

(9) "Dispenser delegate" means any of the following:

(a) A managing pharmacist of a pharmacy.

(b) An agent or employee of a practitioner who has been delegated the task of satisfying the data compilation and submission requirements of ss. CSB 4.04 and 4.05.

(10) "Dispensing data" means data compiled pursuant to s. CSB 4.04.

(11) "Drug" has the meaning given in s. 450.01 (10), Stats.

(11c) "Healthcare Professional" means a pharmacist, practitioner, registered nurse licensed under s. 441.06, Stats., substance abuse counselor, as defined in s. 440.88 (1) (b), Stats., or individual authorized under s. 457.02 (5m), Stats., to treat alcohol or substance dependency or abuse as a specialty.

(11g) "Hospital" has the meaning given in s. 50.33 (2), Stats.

(11n) "Law enforcement agency" has the meaning given in s. 165.77 (1) (b), Stats.

(11r) "Managing pharmacist" means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(11w) "Medical coordinator" means a person who medically coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

(12) (a) "Monitored prescription drug" means all of the following:

1. A controlled substance included in s. 961.385 (1) (ag), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. CSB 4.03.

(b) "Monitored prescription drug" does not mean a controlled substance that by law may be dispensed without a prescription order.

(12m) "Monitored prescription drug history report" means all of the following information about a patient, patient address, practitioner, or dispenser compiled by the PDMP system and disclosed as authorized in ss. CSB 4.09 and 4.11:

(a) PDMP data.

(b) Reports submitted to the program pursuant to s. 961.37, Stats.

(c) Information submitted to the program by a healthcare professional.

(d) Information from the analytics platform.

(13) "Patient" has the meaning given in s. 961.385 (1) (aj), Stats.

(14e) "PDMP" means the Wisconsin prescription drug monitoring program.

(15) "PDMP data" means the information compiled and analyzed by the PDMP system from dispensing data submitted to it by dispensers.

(15b) "PDMP system" means the web–based application, analytics platform, and all related hardware and software that facilitates the submission of dispensing data and the access to and disclosure of PDMP data, monitored prescription drug history reports, audit trails, and prescribing metrics reports.

(15e) "Personally identifiable information" means information that can be associated with a particular person through one or more identifiers or other information or circumstances.

(15g) "Pharmacist" has the meaning given in s. 961.385 (1) (aL), Stats. For the purposes of this program, the board recognizes a pharmacist licensed by another state that engages in the practice of pharmacy within the contiguous borders of this state or who practices at a pharmacy licensed under s. 450.065, Stats. as a person authorized to engage in the practice of pharmacy.

(15r) "Pharmacist delegate" means an agent of a pharmacist to whom the pharmacist has delegated the task of accessing monitored prescription drug history reports.

(16) "Pharmacy" has the meaning given in s. 961.385 (1) (an), Stats., including a pharmacy that chooses to solely dispense to animal patients.

(17) "Practitioner" has the meaning given in s. 961.385 (1) (ar), Stats. For the purposes of this program, the board recognizes a practitioner licensed by another state that engages in the practice of their credentialed profession within the contiguous borders of this state as a person authorized to prescribe and administer drugs.

(18) "Practitioner delegate" means an agent of a practitioner to whom the practitioner has delegated the task of accessing monitored prescription drug history reports.

(18m) "Prescribing metrics report" means all of the following information about a practitioner compiled by the PDMP system and disclosed as authorized in s. CSB 4.09:

(a) PDMP data.

(b) Audit trails.

(c) Reports submitted to the program pursuant to s. 961.37, Stats., about a patient to whom the practitioner has issued a prescription order.

(d) Information from the analytics platform.

(19) "Prescription" has the meaning given in s. 450.01 (19), Stats.

(20) "Prescription order" has the meaning given in s. 961.385 (1) (b), Stats.

(21) "Program" means the prescription drug monitoring program established under this chapter.

(21m) "Prosecutorial unit" has the meaning given in s. 978.001 (2), Stats.

(23) "Zero report" means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13–065: cr. (3m), (13e), am. (16), (17), r. (22) Register February 2014 No. 698, eff. 3–1–14; (13e) renum. to (14e) under s. 13.92 (4) (b) 1., Stats., Register February 2014 No. 698; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14–003: am. (8) (a), renum. (9) to (9) (intro.) and am., cr. (9) (a), (b), (11g), (11r), am. (15) (intro.), cr. (15g), (15r), am. (17) Register August 2014 No. 704, eff. 9–1–14; correction in (3), (9) (b), (10), (12) (a) 1., 2., (15) (b), (15g), (17), (20) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15–101: am. (4) Register June 2016 No. 726, eff. 7–1–16; EmR1706: emerg. am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m), eff. 4–1–17; CR 17–028: am. (1), (2), cr. (2m), (3s), (4m), (5m), am. (7), cr. (11c), (11n), am. (11r), cr. (11w), am. (12) (a) 1., cr. (12m), am. (13), r. (14), cons. and renum. (15) (intro.) and (a) to (15) and am., r. (15) (b), cr. (15b), (15e), am. (15g), (15r), (16), (17), (18), cr. (18m), (21m) Register December 2017 No. 744, eff. 1–1–18.

CSB 4.03 Drugs that have a substantial potential for abuse. Pursuant to s. 961.385 (1) (ag), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (2) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682; CR 13–065: am. (intro.) Register February 2014 No. 698, eff. 3–1–14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15–101: r. (3) Register June 2016 No. 726, eff. 7–1–16; EmR1706: emerg. r. (2), eff. 4–1–17; CR 17–028: r. (2) Register December 2017 No. 744, eff. 1–1–18.

CSB 4.04 Compilation of dispensing data. (1) As used in this section:

(a) "DEA registration number" means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

(c) "NDC number" means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(2) Subject to s. CSB 4.08, a dispenser shall compile dispensing data that contains all of the following information each time the dispenser dispenses a monitored prescription drug:

(a) The dispenser's full name.

(b) The dispenser's DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number of the monitored prescription drug.

(f) The quantity dispensed.

(g) The estimated number of days of drug therapy.

(gb) The drug dosage units.

(gd) The partial fill indicator.

(ge) The classification code for payment type.

(gm) The number of refills authorized by the prescriber.

(gs) The refill number of the prescription.

(h) The practitioner's full name.

(i) The practitioner's DEA registration number.

(j) The date prescribed.

(L) The patient's full name or if the patient is an animal, the animal's name and the owner's last name.

(m) The patient's address, or if the patient is an animal, patient's owner's address, including street address, city, state, and ZIP code.

(n) The patient's date of birth, or if the patient is an animal, patient's owner's date of birth.

(o) The patient's gender.

(p) The name recorded under s. 450.11 (1b) (bm), Stats.

(4) The board may refer a dispenser and dispenser delegate that fail to compile dispensing data as required by sub. (2) to the appropriate licensing or regulatory board for discipline.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 13–065: am. (1) (b), (e), (3) (b), (d), (i), (k) Register February 2014 No. 698, eff. 3–1–14; CR 14–003: am. (title), renum. (2) to (2) (intro.) and am., cr. (2) (ge), (gm), (gs), renum. (3) (a) to (g) and (h) to (j) to (2) (a) to (g) and (h) to (j), r. (3) (k), renum. (3) (L) to (o) to (2) (L) to (o) and am. (L) to (n), am. (4) Register August 2014 No. 704, eff. 9–1–14; correction in (2) (intro.) made under s. 35.17, Stats., and in (4) made under s. 13.92 (4) (b) 7., Stats., Register August 2014 No. 704; correction in (2) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15–070: cr. (2) (p) Register April 2016 No. 724, eff. 4–9–17; numbering correction in (2) (p) under s. 13.92 (4) (b) 1. Register April 2016 No. 724; republished to correct CR 15–070: cr. (2) (p) effective date Register May 2016 No. 725; EmR1706: emerg. r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4), eff. 4–1–17; CR 17–028: r. (1) (b), (d), (e), am. (2) (b), (e), (i), (4) Register December 2017 No. 744, eff. 1–1–18; **CR 19–156: cr. (2) (gb), (gd) Register August 2020 No. 776, eff. 9–1–20.**

CSB 4.05 Electronic submission of dispensing data. (1) Unless exempt under s. CSB 4.08, a dispenser shall electronically submit dispensing data to the PDMP in any of the following ways:

(a) As a file that complies with the data standards identified in version 4 and release 2 of ASAP implementation guide for prescription monitoring programs.

(b) Using the prescription record entry functions of the PDMP system.

Note: The guide for dispensers which specifies the data standards in version 4 release 2 of the ASAP implementation guide for prescription monitoring programs and other electronic formats identified by the board may be obtained online at https://pdmp.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(4) The board may refer a dispenser and dispenser delegate that fail to submit dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 13−065: am. (2) Register February 2014 No. 698, eff. 3−1−14; CR 14−003: am. (1), (4) Register August 2014 No. 704, eff. 9−1−14; correction in (intro.) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. renum. (1) to (1) (intro.), cr. (1) (a), (b), r. (2), (3), r. and recr. (4), eff. 4−1−17; CR 17−028: renum. (1) to (1) (intro.), cr. (1) (a), (b), r. (2), (3), r. and recr. (4) Register December 2017 No. 744, eff. 1−1−18.

CSB 4.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the PDMP no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed.

(2) If a dispenser does not dispense a monitored prescription drug on a business day, the dispenser shall submit no later than 11:59 p.m. of the next business day a zero report to the PDMP that accounts for each business day on which the dispenser did not dispense a monitored prescription drug.

(3) If a dispenser is not able to submit dispensing data zero report before 11:59 p.m. of the next business day as required by subs. (1) or (2), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data or a zero report because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data or zero report.

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

(4) Unless otherwise specified by the board, an emergency waiver granted under sub. (3) shall only be effective for 7 days.

(5) The board may refer a dispenser and dispenser delegate that fail to submit dispensing data or a zero report as required by subs. (1) and (2), or be granted an emergency waiver under sub. (3), or a dispenser and a dispenser delegate that submit false information to the PDMP to the appropriate licensing or regulatory board for discipline.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 13−065: am. (1), (2), (3) (intro.), r. (4) to (6), (9), renum. (7) to (4) and am., renum. (8) to (5) Register February 2014 No. 698, eff. 3−1−14; CR 14−003: am. (2), (5) Register August 2014 No. 704, eff. 9−1−14; EmR1706: emerg. am. (1), (2), (3), (5), eff. 4−1−17; CR 17−028: am. (1), (2), (3), (5) Register December 2017 No. 744, eff. 1−1−18.

CSB 4.07 Correction of dispensing data. (1) A dispenser shall electronically correct dispensing data in the PDMP system within 5 business days of discovering an omission, error, or inaccuracy in previously submitted dispensing data.

(2) The board may refer a dispenser and dispenser delegate that fail to correct dispensing data as required by sub. (1) to the appropriate licensing or regulatory board for discipline.

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 14−003: am. Register August 2014 No. 704, eff. 9−1−14; EmR1706: emerg. r. and recr. eff. 4−1−17; CR 17−028: r. and recr. Register December 2017 No. 744, eff. 1−1−18.

CSB 4.08 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew its license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that the dispenser does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

Note: The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

(2) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is administered directly to a patient.

(2m) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is compounded, packaged, or labeled in preparation for delivery but is not delivered.

(3) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is a substance listed in the schedule in s. 961.22, Stats., and is not a narcotic drug, as defined in s. 961.01 (15), Stats., and is dispensed pursuant to a prescription order for a number of doses that is intended to last the patient 7 days or less.

History: CR 12−009: cr. Register October 2012 No. 682, eff. 1−1−13; CR 14−003: am. (1) (a), cr. (3) Register August 2014 No. 704, eff. 9−1−14; CR 15−101: am. (1) Register June 2016 No. 726, eff. 7−1−16; EmR1706: emerg. cr. (2m), eff. 4−1−17; CR 17−028: cr. (2m) Register December 2017 No. 744, eff. 1−1−18.

CSB 4.09 Access to monitored prescription drug history reports and PDMP data about a patient. (1) Healthcare professionals may access monitored prescription drug history reports about a patient for any of the following reasons:

(a) The healthcare professional is directly treating or rendering assistance to the patient.

(b) The healthcare professional is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient.

(c) Scientific research purposes if all of the following requirements are met:

1. The patient is a direct patient of the healthcare professional.

2. The healthcare professional has obtained informed consent from the patient to access monitored prescription drug history reports for scientific research purposes.

(d) Purposes of conducting an overdose fatality review.

(2) Pharmacist delegates and practitioner delegates may access monitored prescription drug history reports about a patient for any of the following reasons:

(a) A pharmacist or practitioner who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

(b) A pharmacist or practitioner who is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient has delegated the task of obtaining monitored prescription drug history reports about the patient to the pharmacist delegate or practitioner delegate.

(3) Healthcare professionals, pharmacist delegates, and practitioner delegates may only disclose a monitored prescription drug history report about a patient obtained pursuant to sub. (1) or (2) in the following situations:

(a) To the patient as part of treating or rendering assistance to the patient.

(b) To another healthcare professional or a medical coordinator for consultation about the health of the patient or as part of treating or rendering assistance to the patient.

(c) To the pharmacist or practitioner who is directly treating or rendering assistance to the patient.

(d) To a law enforcement agency as required by s. 146.82, Stats.

(4) To obtain access to monitored prescription drug history reports as authorized in subs. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall do one of the following:

(a) Create an account with the PDMP system.

(b) Create an account with a prescription monitoring program operated by a relevant agency in another jurisdiction with which the board exchanges monitored prescription drug history reports or PDMP data pursuant to s. CSB 4.14.

(c) Create an account with a pharmacy or other entity at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state–designated entity under ch. 153, Stats.

(d) Create an account with a hospital or other entity at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports or that is connected to and lawfully obtains data from the state–designated entity under ch. 153, Stats.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1), renum. (2) to (2) (intro.) and am., cr. (2) (a) to (d), am. (3) Register August 2014 No. 704, eff. 9–1–14; corrections in (1), (2) (b), (3) (a) Register September 2015 No. 717; EmR1706: emerg. r. and recr., eff. 4–1–17; CR 17–028: r. and recr. Register December 2017 No. 744, eff. 4–1–17; s. 35.17 corrections in (3) (intro.), (4) (intro.), Register December 2017 No. 744; **CR 19–156: cr. (1) (c), (d) Register August 2020 No. 776, eff. 9–1–20.**

CSB 4.093 Monitored prescription drug history reports and audit trails about healthcare professionals. (1) Healthcare professionals may access audit trails about themselves and their practitioner delegates or pharmacist delegates.

(2) A practitioner may access the audit trails accessible to healthcare professionals and a prescribing metrics report about themself.

(2m) Department staff who are charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates may access the audit trails related to s. CSB 4.12 (3) (f) and (g).

(3) Medical coordinators may access prescribing metrics reports and audit trails about a healthcare professional whom the medical coordinator coordinates, directs, or supervises or for whom the medical coordinator establishes standard operating procedures that contain no personally identifiable information about a patient if the medical coordinator is conducting any of the following activities:

(a) Evaluating the job performance of the healthcare professional.

(b) Performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines for the healthcare professional.

(4) To obtain access to prescribing metrics reports and audit trails as authorized in subs. (1) and (2), healthcare professionals, pharmacist delegates, and practitioner delegates shall create an account with the PDMP system.

(5) To obtain access to prescribing metrics reports, and audit trails about a healthcare professional, a medical coordinator shall create an account with the PDMP system.

History: EmR1706: emerg. cr. eff. 4–1–17; CR 17–028: cr. Register December 2017 No. 744, eff. 4–1–17; s. 35.17 correction in (4), Register December 2017 No. 744; **CR 19–156: cr. (2m) Register August 2020 No. 776, eff. 9–1–20.**

CSB 4.097 Deny, suspend, revoke or otherwise restrict or limit access. (1) The board may deny, suspend, revoke, or otherwise restrict or limit a healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit tails for any of the following reasons:

(a) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is suspected of attempting to access, accessing, or disclosing a monitored prescription drug history report, prescribing metrics report, PDMP data, or audit trail in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The healthcare professional is no longer licensed in this state or in another state and recognized by this state as a person to whom the board may grant access pursuant to s. CSB 4.09 or 4.093.

(c) The board, or other licensing board, or regulatory agency takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(e) The federal department of justice, drug enforcement administration takes adverse action against the healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator.

(f) The healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator is convicted of a crime substantially related to the prescribing, administering, or dispensing of a monitored prescription drug.

(g) The pharmacist delegate or practitioner delegate is no longer delegated the task of accessing monitored prescription drug history reports.

(h) The medical coordinator no longer coordinates, directs, supervises, or establishes standard operating procedures for a healthcare professional.

(2) The board may temporarily suspend access to monitored prescription drug history reports, prescribing metrics reports, PDMP data, and audit trails upon discovering circumstances that indicate a healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator has performed any of the actions identified in sub. (1) (a).

History: EmR1706: emerg. cr., eff. 4–1–17; CR 17–028: cr. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.10 Requests for review. (1) A dispenser, healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator may request that the board review any of the following:

(b) The denial of an emergency waiver requested pursuant to s. CSB 4.06 (3).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's account pursuant to s. CSB 4.097.

(2) To request a review, the dispenser, health care professional, pharmacist delegate, practitioner delegate, or medical coordinator shall file a written request with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The dispenser's, healthcare professional's, pharmacist delegate's, practitioner delegate's, or medical coordinator's name and address, including street address, city, state and ZIP code.

(b) The citation to the specific statute or rule on which the request is based.

(3) The board shall conduct the review at its next regularly scheduled meeting and notify the dispenser, healthcare profes-

sional, pharmacist delegate, practitioner delegate, or medical coordinator of the time and place of the review.

(4) No discovery is permitted.

(5) The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

(6) The board shall provide the dispenser, healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the board, the time for making a personal appearance shall be 20 minutes.

(7) If the dispenser, healthcare professional, pharmacist delegate, practitioner delegate, or medical coordinator fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (1) (b) made under s. 13.92 (4) (b) 7., Stats., Register February 2014 No. 698; CR 14–003: am. (1) (intro.), (2) (intro.), (b), (3), (6), (7) Register August 2014 No. 704, eff. 9–1–14; correction in (1) (a) to (c) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; CR 15–101: am. (1) (c), (2) (a) Register June 2016 No. 726, eff. 7–1–16; s. 35.17 correction in (1) (c), Register June 2016 No. 726; EmR1706: emerg. am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7), eff. 4–1–17; CR 17–028: am. (1) (intro.), r. (1) (a), am. (1) (c), (2) (intro.), (a), (3), (6), (7) Register December 2017 No. 744, eff. 1–1–18; correction in (1) (c) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744.

CSB 4.105 Practitioners' requirement to review monitored prescription drug history reports. (1) A practitioner, or a practitioner delegate assisting the practitioner in accordance with the standards of practice for the practitioner's profession, shall review the monitored prescription drug history report about a patient before the practitioner issues a prescription order for the patient unless any of the following conditions are met:

(a) The patient is receiving hospice care, as defined in s. 50.94 (1) (a).

(b) The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.

(c) The monitored prescription drug is lawfully administered to the patient.

(d) The practitioner is unable to review the patient's monitored prescription drug history reports before issuing a prescription order for the patient due to an emergency.

(e) The practitioner is unable to review the patient's records under their program because the PDMP system is not operational or due to other technological failure that the practitioner reports to the board.

(2) Reviews of reports or other information not provided by the board as part of the program that summarize or analyze PDMP data do not satisfy the requirement to review a monitored prescription drug history report under sub. (1).

(3) The board may refer a practitioner that fails to review a monitored prescription drug history report about a patient prior to issuing a prescription order for that patient to the appropriate licensing or regulatory board for discipline.

History: EmR1706: emerg. cr., eff. 4–1–17; CR 17–028: cr. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.11 Methods of obtaining monitored prescription drug history reports. (1) The board shall disclose the monitored prescription drug history report about a patient to the patient if he or she does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government–issued photographic identification or mails to the department copies of two forms of valid proof of identity, one of which is valid government–issued photographic identification.

(b) Makes a request for the monitored prescription drug history reports about the patient on a form provided by the board. If the request is mailed, the form shall be notarized.

(2) The board shall disclose the monitored prescription drug history report about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government–issued photographic identification.

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the monitored prescription drug history report on a form provided by the board.

(5) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the monitored prescription drug history report through its PDMP system account.

(d) If the PDMP system is unable to fulfill a request from designated staff through their account with the PDMP system, the board may disclose the minimum necessary amount of information necessary to designated staff of a federal or state governmental agency upon written request that cites the agency's specific authorization to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records.

(6) The board shall disclose the minimum necessary amount of PDMP data or information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of the department who is charged with investigating dispensers, dispenser delegates, pharmacists, pharmacist delegates, practitioners, and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the monitored prescription drug history report through its PDMP system account.

(7) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient or patient address to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the monitored prescription drug history report through its PDMP system account.

(8) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 961.385, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the monitored prescription drug history report through its PDMP system account with the board.

(9) The board may disclose PDMP data without personally identifiable information that could be reasonably used to identify any patient, healthcare professional, practitioner delegate, pharmacist delegate, or dispenser for public health and scientific research purposes. The board may require evidence of institutional review board approval.

(10) The board shall disclose the minimum necessary amount of information in a monitored prescription drug history report about a patient, patient address, practitioner, or dispenser to designated staff of a law enforcement agency or prosecutorial unit if the designated staff does all of the following:

(a) Creates an account with the PDMP system.

(b) Provides documentation demonstrating the law enforcement agency or prosecutorial unit is engaged in one of the following activities:

1. An active and specific investigation or prosecution of a violation of any state or federal law involving a monitored prescription drug and that the information being requested is reasonably related to that investigation or prosecution.

2. The monitoring of a patient as part of a drug court, as defined in s. 165.955 (1).

(c) Makes a request for the monitored prescription drug history report through its account with the PDMP system.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: r. (3), (4), am. (6) (intro.), renum. (9) (intro.) to (9) and am., r. (9) (a) to (c) Register August 2014 No. 704, eff. 9–1–14; correction in (5) (intro.), (6) (intro.), (7) (intro.), (8) (intro.), (10) (intro.) Register September 2015 No. 717; CR 15–101: am. (1) (intro.), (b), (2) (intro.), (c), (7) (intro.), (c), (8) (intro.), (c) Register June 2016 No. 726, eff. 7–1–16; EmR1706: emerg. am (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) eff. 4–1–17; CR 17–028: (Title), (1), (2) (intro.), (c), (5) (intro.), (a), (c), cr. (d), am. (6) (intro.), (a), (c), (7) (intro.), (a), (c), (8) (intro.), (a), (c), (9), (10) Register December 2017 No. 744, eff. 1–1–18; **CR 19–156: am. (9) Register August 2020 No. 776, eff. 9–1–20.**

CSB 4.12 Use of PDMP data by the board and department. (1) The board shall develop and maintain a PDMP database to store dispensing data and PDMP data in a secure environment and an encrypted format.

(2m) The board shall develop and maintain a PDMP system to facilitate all of the following:

(a) The submission of dispensing data to the PDMP database.

(b) The creation of monitored prescription drug history reports about specific patients, practitioners, and dispensers.

(c) The access to and the obtaining of monitored prescription drug history reports, prescribing metrics reports, and audit trails.

(3) The board shall maintain audit trails that contain all of the following information:

(a) A log of dispensing data submitted to the PDMP database by each dispenser.

(b) A log of persons to whom the Board has granted direct access to the PDMP system under ss. CSB 4.09 or 4.093 and a log of each time a person attempts to access PDMP data or a monitored prescription drug history report.

(c) A log of prescription monitoring programs operated by a relevant agency in another jurisdiction with which the board exchanges PDMP data pursuant to s. CSB 4.14 and a log of each time a person from another jurisdiction attempts to access PDMP data.

(d) A log of pharmacies or other entities at which pharmacists dispense or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a pharmacy or other entity attempts to access PDMP data or a monitored prescription drug history report.

(e) A log of hospitals or other entities at which practitioners prescribe, dispense, or administer monitored prescription drugs in the course of professional practice with which the board has determined to have at least equivalent capability to maintain the confidentiality of monitored prescription drug history reports and a log of each time a person from a hospital or other entity attempts to access PDMP data or a monitored prescription drug history report.

(f) A log of monitored prescription drug history reports and PDMP data disclosed pursuant to s. CSB 4.11, including the name of the person to whom the information was disclosed.

(g) A log of requests for PDMP data or monitored prescription drug history reports even when no information was disclosed.

(6) Staff assigned administrative duties over the PDMP, vendors, contractors, and other agents of the board shall only have access to the minimum amount of PDMP data necessary for all of the following purposes:

(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, PDMP system, the disclosure of information via other entities pursuant to s. CSB 4.09 (4), and the exchange of information pursuant to s. CSB 4.15 as part of the assigned duties and responsibilities of their employment.

(am) The operation of an analytics platform that provides data cleansing and standardization, data integration, advanced analytics, and alert management capabilities as part of the PDMP database and PDMP system.

(b) The collection of dispensing data as part of the assigned duties and responsibilities under s. 961.385, Stats., and this chapter.

(c) Evaluating and responding to legitimate requests for monitored prescription drug history reports, audit trails, and PDMP data.

(cg) Preparing monitored prescription drug history reports, audit trails, and PDMP data for the board to determine whether suspicious or critically dangerous conduct or practices has occurred or is occurring pursuant to s. CSB 4.15.

(cr) Conducting a review of the program as required by s. 961.385 (5), Stats.

(d) Other legally authorized purposes.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (4), cr. (4g), (4r) Register August 2014 No. 704, eff. 9–1–14; correction in (6) (b) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), eff. 4–1–17; CR 17–028: am. (title), (1), r. (2), cr. (2m), r. and recr. (3), r. (4), (4g), (4r), (5), am. (6) (intro.), (a), cr. (6) (am), am. (6) (c), cr. (6) (cg), (cr), Register December 2017 No. 744, eff. 1–1–18; ; correction in (3) (b) made under s. 13.92 (4) (b) 7., Stats., December 2017 No. 744.

CSB 4.13 Confidentiality of PDMP records. (1) The dispensing data, PDMP data, audit trails, monitored prescription drug history reports, and prescribing metrics reports maintained, created, or stored as a part of the program are not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses or a person whose delegate discloses dispensing data, PDMP data, audit trails, monitored prescription drug history reports, or prescribing metrics reports in violation of s. 146.82 or 961.385, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be referred to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution if the board determines that a criminal violation may have occurred.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register September 2015 No. 717; EmR1706: emerg. am., eff. 4–1–17; CR 17–028: am. Register December 2017 No. 744, eff. 1–1–18.

CSB 4.14 Exchange of PDMP data. (1) The board may exchange monitored prescription drug history reports and PDMP data with a prescription monitoring program operated by a relevant agency in another state or jurisdiction if the prescription monitoring program satisfies all of the following conditions:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

(2) In determining the compatibility of a prescription monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

(3) The board may assess a prescription monitoring program's continued compatibility with the program at any time.

History: CR 12–009: cr. Register October 2012 No. 682, eff. 1–1–13; CR 14–003: am. (1) (intro.) Register August 2014 No. 704, eff. 9–1–14; EmR1706: emerg. am. (title), (1) (intro.), eff. 4–1–17; CR 17–028: am. (title), (1) (intro.) Register December 2017 No. 744, eff. 1–1–18.

CSB 4.15 Disclosure of suspicious or critically dangerous conduct or practices. (1) The board may review dispensing data, monitored prescription drug history reports, PDMP data, and data compiled pursuant to s. CSB 4.12 to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

(2) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist or pharmacy:

(a) The pharmacist or pharmacy's monitored prescription drug dispensing practices deviate from accepted pharmacist or pharmacy practices.

(b) There are unusual patterns in the payment methodology used by patients to whom monitored prescription drugs are dispensed by the pharmacist or pharmacy.

(c) The history of actions taken against the pharmacist or pharmacy by other state agencies, agencies of another state, or law enforcement.

(d) The type and number of monitored prescription drugs dispensed by the pharmacist or at the pharmacy.

(e) The pharmacist or pharmacy has dispensed forged prescription orders for a monitored prescription drug.

(f) The distance patients travel to have monitored prescription drugs dispensed at the pharmacy.

(g) The number of patients dispensed monitored prescription drugs at the pharmacy or by the pharmacist who satisfy any of the criteria identified in sub. (4).

(3) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a practitioner:

(a) The practitioner's monitored prescription drug prescribing practices deviate from accepted prescribing practices.

(b) The practitioner prescribes potentially dangerous combinations of monitored prescription drugs to the same patient.

(c) The type and number of monitored prescription drugs prescribed by the practitioner.

(d) The history of actions taken against the practitioner by other state agencies, agencies of another state, or law enforcement.

(e) The distance patients travel to obtain monitored prescription drug prescriptions from the practitioner.

(f) The number of patients to whom the practitioner prescribed a monitored prescription who satisfy any of the criteria identified in sub. (4).

(4) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a patient:

(a) The number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug.

(b) The number of pharmacies from where the patient was dispensed a monitored prescription drug.

(c) The number of prescriptions for a monitored prescription drug obtained by the patient.

(d) The number of monitored prescription drug doses dispensed to the patient.

(e) Whether the monitored prescription drugs dispensed to the patient include dangerous levels of any drug.

(f) The number of times the patient is prescribed or dispensed a monitored prescription drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end.

(g) The payment methodology used by the patient to obtain controlled substances at a pharmacy.

(5) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose monitored prescription drug history reports, audit trails, and PDMP data to any of the following:

(a) A relevant patient.

(b) A relevant pharmacist or practitioner.

(c) A relevant state board or agency.

(d) A relevant agency of another state.

(e) A relevant law enforcement agency.

(6) Upon determining that a criminal violation may have occurred, the board may refer a pharmacist, pharmacy, or practitioner to the appropriate law enforcement agency for investigation and possible prosecution. The board may disclose monitored prescription drug history reports, audit trails, and PDMP data to the law enforcement agency as part of the referral.

History: CR 15–101: cr. Register June 2016 No. 726, eff. 7–1–16; CR 17–028: am. (1), (5) (intro.), cr. (6) Register December 2017 No. 744, eff. 1–1–18.