**657—37.3(124) Requirements for the PMP.** Each dispenser, unless identified as exempt from reporting and who has applied for and been granted an exemption from reporting to the PMP pursuant to subrule 37.3(1), shall submit to the PMP administrator either a record of each reportable prescription dispensed during a reporting period or a zero report pursuant to subrule 37.3(5), as appropriate. A dispenser located outside the state of Iowa, unless identified as exempt from reporting and who has applied for and been granted an exemption from reporting to the PMP pursuant to subrule 37.3(1), shall submit to the PMP administrator either a record of each reportable prescription dispensed during a reporting period to a patient located in Iowa or a zero report pursuant to subrule 37.3(5), as appropriate.

**37.3(1)** *Exemptions.* The dispensing of a controlled substance as described in this subrule shall not be considered a reportable prescription. A dispenser engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in paragraph 37.3(1)*"a,"* 37.3(1)*"b,"* or 37.3(1)*"c,"* or that is not registered to handle controlled substances as described in paragraph 37.3(1)*"d,"* may apply for an exemption from reporting to the PMP. A dispenser claiming exemption pursuant to this subrule shall certify to the board, on a form provided by the board, the basis for exemption from reporting to the PMP. The PMP administrator is hereby authorized to approve or deny the pharmacy's request for exemption from reporting to the PMP.

*a.* A licensed hospital pharmacy shall not be required to report the dispensing of a controlled substance for the purposes of inpatient hospital care, the dispensing of a prescription for a starter supply of a controlled substance at the time of a patient's discharge from such a facility, or the dispensing of a prescription for a controlled substance in a quantity adequate to treat the patient for a maximum of 72 hours. A hospital pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the hospital pharmacy dispenses only as provided by this paragraph.

*b.* A licensed pharmacy shall not be required to report the dispensing of a controlled substance for a patient residing in a long-term care facility or for a patient residing in an inpatient hospice facility. A pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the pharmacy dispenses only to patients residing in a long-term care facility or to patients residing in an inpatient hospice facility.

*c.* A nonresident pharmacy that does not distribute controlled substances to patients located in Iowa shall not be required to report to the PMP. A nonresident pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the nonresident pharmacy does not dispense controlled substances to patients located in Iowa.

*d.* A licensed pharmacy that does not handle controlled substances and that is not registered to handle controlled substances with the federal DEA shall not be required to report to the PMP. A pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the pharmacy does not dispense controlled substances.

*e.* A prescriber or other authorized person who administers or dispenses a controlled substance, including samples of a controlled substance, for the purposes of outpatient care shall not be required to report such administration or dispensing. A prescriber shall not be required to submit a form or notification claiming exemption from reporting to the PMP. This exception shall not apply to a pharmacist who administers a controlled substance, as directed by the prescriber, pursuant to a prescription.

*f.* A wholesale distributor of a controlled substance shall not be required to report the wholesale distribution of such a substance. A wholesale distributor shall not be required to submit a form or notification claiming exemption from reporting to the PMP.

**37.3(2)** *Data elements.* The information submitted for each prescription shall include, at a minimum, the following items:

*a.* Dispenser DEA number.
*b.* Date the prescription is filled.
*c.* Prescription number.
*d.* Indication as to whether the prescription is new or a refill.
*e.* NDC number for the drug dispensed.
*f.* Quantity of the drug dispensed.
*g.* Number of days of drug therapy provided by the drug as dispensed.

*h.* Patient first and last names.
*i.* Patient address including street address, city, state, and ZIP code.
*j.* Patient date of birth.
*k.* Patient gender.
*l.* Prescriber DEA number.
*m.* Date the prescription was issued by the prescriber.
*n.* Method of payment.

**37.3(3)** *Reporting periods.* A record of each reportable prescription dispensed shall be submitted by each dispenser no later than the next business day following dispensing. Records may be submitted with greater frequency than required by this subrule.

**37.3(4)** *Transmission methods.* Prescription information shall be transmitted using one of the following methods:

*a.* Data upload to a reporting website via a secure Internet connection or by utilizing the secure FTP procedure. The PMP administrator or designee will provide dispensers with initial secure login and password information. Dispensers will be required to register on the reporting website prior to initial data upload.

*b.* Electronic media including CD-ROM, DVD, or diskette, accompanied by a transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media as directed by the PMP administrator or designee.

*c.* If a dispenser does not have an automated record-keeping system capable of producing an electronic report as provided in this rule, the dispenser may submit prescription information on the industry standard universal claim form. The dispenser may complete and submit the claim form on the reporting website or, if the dispenser does not have Internet access, the completed paper claim form may be submitted as directed by the PMP administrator or designee.

*d.* Chain pharmacies and pharmacies under shared ownership may submit combined data transmissions on behalf of all facilities by utilizing the secure FTP procedure. Combined data transmissions shall identify the specific pharmacy that dispensed each individual prescription record included in the combined data transmission.

**37.3(5)** *Zero reports.* If a dispenser has not been identified as exempt from reporting to the PMP and the dispenser did not dispense any reportable prescriptions during a reporting period, the dispenser shall submit a zero report via the established reporting website or secure FTP procedure. The schedule identified in subrule 37.3(3) shall determine timely submission of zero reports.

[**ARC 7903B**, IAB 7/1/09, effective 8/5/09; **ARC 0242C**, IAB 8/8/12, effective 1/1/13; **ARC 3102C**, IAB 6/7/17, effective 7/12/17; **ARC 3743C**, IAB 4/11/18, effective 5/16/18]