

CHAPTER 37
IOWA PRESCRIPTION MONITORING PROGRAM

657—37.1(124) Purpose. These rules establish a prescription monitoring program that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner may, but is not required to, access prescription monitoring program (PMP) information regarding the practitioner's patient to assist in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a health care practitioner with a resource for information regarding a patient's use of controlled substances. This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of controlled substances without impeding the appropriate medical use of controlled substances.

[ARC 7903B, IAB 7/1/09, effective 8/5/09]

657—37.2(124) Definitions. As used in this chapter:

"Board" means the Iowa board of pharmacy.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V set forth in Iowa Code chapter 124, division II.

"Council" means the PMP advisory council established pursuant to Iowa Code section 124.555 to provide oversight and to co-manage PMP activities with the board.

"Database information" or *"PMP information"* means information submitted to and maintained by the PMP database.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration (DEA) authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispenser" means a person who delivers to the ultimate user a substance required to be reported to the PMP database. "Dispenser" includes a pharmacy located outside the state of Iowa that is licensed by the board with a nonresident pharmacy license authorizing the pharmacy to dispense prescription drugs to patients physically located in Iowa. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.3(1).

"Electronic health record system" or *"EHRS"* means a real-time, patient-centered health record system that makes patient health information and other health care tools and resources readily and securely available to authorized providers in a digital format capable of being shared with other providers across one or more health care organizations or facilities.

"Electronic pharmacy information system" or *"e-pharmacy system"* means a real-time electronic patient prescription record system that includes, at a minimum, patient profiles and prescription dispensing information and that may enable shared access to included information by multiple pharmacies, such as a chain of pharmacies using the same e-pharmacy system.

"Electronic system" means an electronic health record system, an electronic pharmacy information system, or a health information exchange. "Electronic systems" refers to a combination of two or more of these types of systems.

"Health care professional" means a person who, by education, training, certification, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. "Health care professional," other than a licensed prescriber or pharmacist, may include, but is not limited to, a certified pharmacy technician or a registered technician trainee, a nurse, a certified medical assistant, or a pharmacist-intern.

"Health information exchange" or *"HIE"* means a system that allows health care professionals to appropriately access and securely share a patient's vital medical information and records as that electronic information is instantly updated and simultaneously available to each of the health care professionals across organizations, often within a region, community, or health care system.

"National drug code" or *"NDC number"* means the universal product identifier used in the United States to identify a specific human drug product.

“*Patient*” means the person or animal that is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

“*Patient's agent*” means a person legally authorized to make health care decisions or gain access to health care records on behalf of the patient for purposes of directing the patient’s care.

“*Patients rights committee*” or “*committee*” means the physician and pharmacist members of the council responsible for monitoring and ensuring protection and preservation of patients’ rights as provided in Iowa Code section 124.555(3)“e.”

“*PMP administrator*” means the board staff person or persons designated to manage and administer the PMP under the direction and oversight of the board and the council.

“*Practitioner*” means a prescriber or a pharmacist.

“*Practitioner's agent*” means a health care professional who is employed by or under the direct supervision of a PMP-registered practitioner and who is authorized by the practitioner to access PMP information as provided in subrule 37.4(1).

“*Prescriber*” means a licensed health care professional with the authority to prescribe prescription drugs including controlled substances.

“*Prescription monitoring program*” or “*PMP*” means the program established pursuant to these rules for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals, including health care providers, for use in treatment of their patients.

“*Prescription monitoring program database*” or “*PMP database*” means a centralized database of reportable controlled substance prescriptions dispensed to patients and includes data access logs, security tracking information, and records of each individual who requests PMP information.

“*Reportable prescription*” means the record of a Schedule II, III, or IV controlled substance dispensed by a pharmacy to a patient pursuant to a prescriber-authorized prescription. “Reportable prescription” does not include those records excluded in subrule 37.3(1).

“*Schedule II, III, and IV controlled substances*” means those substances that are identified and listed as Schedule II, III, or IV substances in Iowa Code sections 124.205 through 124.210 or in the federal Controlled Substances Act (21 U.S.C. Section 812).

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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.

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657—37.4(124) Access to database information. All information contained in the PMP database, including prescription information submitted for inclusion in the PMP database, communications or notifications to PMP users and dispensers via the database, and records of requests for PMP information, shall be privileged and strictly confidential and not subject to public or open records laws. The board, council, and PMP administrator shall maintain procedures to ensure the privacy and confidentiality of patients, prescribers, dispensers, practitioners, practitioners' agents, and patient information collected, recorded, transmitted, and maintained in the PMP database and to ensure that program information is not disclosed to persons except as provided in this rule.

37.4(1) Prescribers and pharmacists. A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care. A practitioner may authorize no more than six health care professionals to act as the practitioner's agents for the purpose of requesting PMP information regarding a practitioner's patients. A practitioner's agent shall be licensed, registered, certified, or otherwise credentialed as a health care professional in a manner that permits verification of the health care professional's credentials.

a. Prior to being granted access to PMP information, a practitioner or a practitioner's agent shall submit an individual request for registration and program access. The PMP administrator shall take reasonable steps to verify the identity of a practitioner or practitioner's agent and to verify a practitioner's or practitioner's agent's credentials prior to providing a practitioner or practitioner's agent with a secure login and initial password.

(1) A practitioner shall register via a secure website established by the board for that purpose.

(2) A practitioner's agent shall register for access to PMP information on behalf of the supervising practitioner by completing and submitting a hard-copy registration form, provided by the board, that requires the signatures of both the supervising practitioner and the practitioner's agent.

b. Each practitioner or practitioner's agent registered to access PMP information shall securely maintain and use the login and password assigned to the individual practitioner or practitioner's agent. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner or practitioner's agent, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to an unregistered agent. A registered practitioner's agent shall not delegate PMP information access to another individual.

c. A practitioner or practitioner's agent may submit a request for PMP information via a secure website established by the board for that purpose. The requested information shall be provided to the requesting practitioner or practitioner's agent in a format established by the board and shall be delivered via the secure website.

d. A practitioner or practitioner's agent who requests and receives PMP information consistent with the requirements and intent of these rules may provide that information to another practitioner who is involved in the care of the patient who is the subject of the information. Information from the PMP database remains privileged and strictly confidential. Such disclosures among practitioners shall be

consistent with these rules and federal and state laws regarding the confidentiality of patient information. The information shall be used for medical or pharmaceutical care purposes.

e. A practitioner or practitioner's agent shall not provide the patient with a copy of a report generated by the PMP. A patient may receive a report of the patient's own prescription history pursuant to subrule 37.4(4).

37.4(2) *Regulatory agencies and boards.* Professional licensing boards and regulatory agencies that supervise or regulate a health care professional or that provide payment for health care services shall be able to access information from the PMP database only pursuant to an order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. The board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

a. Prior to accepting and processing a request for PMP database information from the director or director's designee of a licensing board or other authorized regulatory agency, the director or director's designee shall complete and submit a hard-copy registration form, provided by the board, that requires the signatures of both the director and the director's designee, as appropriate. The PMP administrator shall take reasonable steps to verify the identity of the director or director's designee prior to providing a director or director's designee with a secure login and initial password.

b. A director of a licensing board with jurisdiction over a health care professional, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, email, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

c. A director of a regulatory agency with jurisdiction over a health care professional or with jurisdiction over a person receiving health care services pursuant to one or more programs provided by the agency, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, email, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

d. The requested information shall be provided to the requesting director or director's designee in a format established by the board and shall be delivered via the secure website or by an alternate delivery method determined by the PMP administrator to be appropriate.

37.4(3) *Law enforcement agencies.* Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of any state or federal law relating to controlled substances shall be able to access information from the PMP database by order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. The board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

a. Prior to accepting and processing a request for PMP database information from a law enforcement officer, the officer shall complete and submit a hard-copy registration form, provided by the board, that requires the signatures of both the officer and the officer's direct superior. The PMP administrator shall take reasonable steps to verify the identity of the officer and the officer's direct superior prior to providing the officer with a secure login and initial password.

b. A law enforcement officer shall submit to the PMP administrator in a format established by the board a written request via mail, email, facsimile, or personal delivery. The request shall be signed by the requesting officer or the officer's superior. The request shall be accompanied by an order, subpoena, or warrant issued by a court or legal authority that requires a determination of probable cause and shall be processed by the PMP administrator.

c. A report identifying PMP information relating to the specific individual identified by the order, subpoena, or warrant shall be delivered to the law enforcement officer via the secure website or by an alternate delivery method determined by the PMP administrator to be appropriate.

37.4(4) Patients. A patient or the patient's agent may request and receive PMP information regarding prescriptions reported to have been dispensed to the patient.

a. A patient may submit a signed, written request for records of the patient's prescriptions dispensed during a specified period of time. The board shall provide the patient with a request form requiring identification of the patient by name, including any aliases used by the patient, and the patient's date of birth and gender. The request form shall also require any address where the patient resided during the time period of the request and the patient's current address and daytime telephone number. A patient may personally deliver the completed request to the PMP administrator or designee at the offices of the board located at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The patient will be required to present current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification and request shall be maintained in the records of the PMP.

b. A patient who is unable to personally deliver the request to the board offices may submit a request via mail or commercial delivery service. The request shall comply with all provisions of paragraph "a" above, and the signature of the requesting patient shall be witnessed and the patient's identity shall be attested to by a currently registered notary public. In addition to the notary's signature and assurance of the patient's identity, the notary shall certify a copy of the patient's government-issued photo identification and that certified copy shall be submitted with the written request. The request shall be submitted to the Iowa Board of Pharmacy at the address identified in paragraph "a."

c. In the case of a patient whose health care decisions have been legally transferred to the patient's agent, the patient's agent may submit a request on behalf of the patient pursuant to the appropriate procedure in paragraph "a" or "b." In addition to the patient's information, the patient's agent shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the patient's agent shall sign the request and the government-issued photo identification shall identify the patient's agent. The patient's agent shall include a certified copy of the legal document that transferred control over decisions regarding the patient's health care to the patient's agent.

d. A report prepared pursuant to this subrule shall be delivered to the patient or the patient's agent, as appropriate, by personal delivery or via mail or alternate secure delivery.

37.4(5) Court orders and subpoenas. The PMP administrator shall provide PMP information in response to court orders and county attorney or other subpoenas issued by a court upon a determination of probable cause. The board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

37.4(6) Statistical data. The PMP administrator or designee may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes. Prior to the release of any such data, the PMP administrator or designee shall remove any personal identifying information or verify that any personal identifying information that could be used to identify an individual patient, prescriber, dispenser, practitioner, or other person who is identified in the PMP information or data has been removed from the PMP information or data. The board may charge a fee for the preparation and release of statistical data as provided in rule 657—37.5(124).

37.4(7) PMP administrator access. Other than statistical data as described in subrule 37.4(6) and technical, error, and administrative function reports and information needed by PMP support staff to determine that records are received and maintained in good order or to review or resolve issues of reported or suspected erroneous data as provided in rule 657—37.7(124), any other reports concerning the information received from dispensers shall only be prepared at the direction of the board, the council, or the PMP administrator. The board and the council may compile statistical reports from PMP information for use in determining the advisability of continuing the PMP and for use in preparing required reports to the governor and the legislature. The reports shall not include information that would identify any patient, prescriber, dispenser, practitioner, practitioner's agent, or other person who is identified in the PMP information or data.

37.4(8) Electronic health and pharmacy information systems. The board may contract with electronic health record systems, health information exchanges, and electronic pharmacy information systems to securely integrate into those electronic systems access to patient prescription histories and

other PMP information available to authorized practitioners and practitioners' agents. Institutional users may be established to identify the facilities and contracted electronic systems and to facilitate secure access by the prescribing practitioners and pharmacists authorized to access PMP information by and through the electronic systems.

a. EHRS, HIE, and e-pharmacy system integration contracts or agreements shall ensure protection of confidential information contained in and received from the PMP.

b. EHRS, HIE, and e-pharmacy system integration contracts or agreements shall restrict access to PMP information to authorized practitioners and practitioner agents as provided by these rules except that individual user registration with the PMP may not be required if the identity of the specific individual receiving or requesting information from the PMP, including a record of the patient whose record is requested, is logged and maintained in an alternate record and is available to the PMP administrator upon request.

c. PMP and electronic system integration may require a separate contract or agreement with a third-party interface or translation service provider to facilitate integration of the PMP into the electronic system. The contract with the service provider shall provide that translation, transmission, or other data integration services provided under the contract are accomplished via a secure encrypted channel that ensures the confidentiality of all information exchanged between the PMP and the electronic system.

37.4(9) Medical examiner or medical examiner investigator. A medical examiner or medical examiner investigator may obtain PMP information when the information requested by the examiner or investigator relates to an investigation being conducted by the examiner or investigator.

[ARC 7903B, IAB 7/1/09, effective 8/5/09; ARC 0056C, IAB 4/4/12, effective 7/1/12; ARC 3102C, IAB 6/7/17, effective 7/12/17; ARC 3743C, IAB 4/11/18, effective 5/16/18]

657—37.5(124) Fees. The board may charge a fee and recover costs incurred for the provision of PMP information, including statistical data, except that no fees or costs shall be assessed to a dispenser for reporting to the PMP or to a practitioner or practitioner's agent for querying the PMP regarding a practitioner's patient. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

[ARC 7903B, IAB 7/1/09, effective 8/5/09; ARC 3102C, IAB 6/7/17, effective 7/12/17]

657—37.6(124) PMP information retained. All dispenser records of prescriptions reported to the PMP shall be retained by the PMP for a period of four years following the date of the record. All records of access to or query of PMP information shall be retained by the PMP for a period of four years following the date of the record. At least semiannually, all PMP information identified as exceeding that four-year period shall be deleted from the PMP and discarded in a manner to maintain the confidentiality of the PMP information and data. Statistical data and reports from which all personally identifiable information has been removed or which do not contain personally identifiable information as provided in subrules 37.4(6) and 37.4(7) may be retained by the PMP for historical purposes.

[ARC 7903B, IAB 7/1/09, effective 8/5/09]

657—37.7(124) Information errors. Any person who believes that PMP information about that person is false or in error shall submit a written statement to the PMP administrator. The statement shall identify the information the person believes to be false or in error and the reason the individual believes the information to be false or in error. The PMP administrator may examine the information identified in the statement and may request the assistance of the board's compliance staff to determine whether or not the PMP information is accurate. Prior to initiating any action to correct, delete, or amend any PMP information, the PMP administrator shall submit the statement and the resulting report to the patients rights committee for review and approval of the recommended action. If correction, deletion, or amendment of any PMP information is authorized, that action shall be accomplished by the PMP administrator within 72 hours of the committee's decision. The PMP administrator shall respond, in writing, to the person who submitted the statement charging that the PMP information was false or in error. The response shall identify the action approved by the committee.

[ARC 7903B, IAB 7/1/09, effective 8/5/09]

657—37.8(124) Dispenser and practitioner records. Nothing in these rules shall apply to records created or maintained in the regular course of business of a pharmacy or health care practitioner. All information, documents, or records otherwise available from pharmacies or health care practitioners shall not be construed as immune from discovery or use in any civil proceedings merely because the information contained in those records was reported to the PMP in accordance with these rules.
[ARC 7903B, IAB 7/1/09, effective 8/5/09]

657—37.9(124) Prohibited acts. The PMP administrator shall report to the licensing board of a dispenser, a practitioner, or a practitioner's agent any known violation of the confidentiality provisions or the reporting requirements of the law and these rules for which the dispenser, practitioner, or practitioner's agent is subject to disciplinary action.

37.9(1) Confidentiality. A pharmacy, pharmacist, practitioner, or practitioner's agent who knowingly fails to comply with the confidentiality provisions of the law or these rules or who delegates PMP information access to another individual, except as provided in paragraph 37.4(1) "b," is subject to disciplinary action by the appropriate professional licensing board. The PMP administrator or a member of the program staff who knowingly fails to comply with the confidentiality provisions of the law or these rules is subject to disciplinary action by the board. In addition to any disciplinary action or sanctions imposed by a professional licensing board, a pharmacy, pharmacist, practitioner, practitioner's agent, PMP administrator, or member of the PMP program staff who knowingly accesses, uses, or discloses program information in violation of Iowa law or these rules is subject to criminal prosecution as provided in Iowa Code section 124.558.

37.9(2) Dispenser reporting. A dispenser or a pharmacist who fails to comply with the reporting requirements of the law or these rules may be subject to disciplinary action by the board.

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These rules are intended to implement Iowa Code sections 124.550 to 124.558.

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