Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 553
"Controlled and Precursor Substances"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124.301 and 124B

State or federal law(s) implemented by the rulemaking: Iowa Code section 124.301 and chapter 124B

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

August 29, 2024	6200 Park Avenue, Suite 100
2 p.m.	Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis. Written comments in response to this Regulatory Analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Sue Mears
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6200 Park Avenue, Suite 100
Des Moines, Iowa 50321
Email: sue.mears@iowa.gov

Purpose and Summary

This proposed rulemaking is intended to establish one combined chapter to identify all requirements relating to controlled and precursor substances. The chapter addresses requirements for records, security, policies and procedures, physical counts and inventories, controlled substance accountability, reporting the theft or loss of controlled substances, disposal of registrant stocks of controlled substances, prescriptions, Schedule II controlled substance prescription changes, dispensing scheduled listed chemical products without a prescription, pseudoephedrine tracking system access, and precursor substances. The citation to 481—Chapter 550 refers to that chapter as proposed in a Regulatory Analysis published herein (IAB 8/7/24).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

Registrants will bear the costs of the rulemaking as it relates to requirements specifically related to procuring, storing, and handling controlled substances (as opposed to registrants engaged only in prescribing of controlled substances). The cost for adequate security will vary depending on the types (schedules) and volume of controlled substances that the registrant intends to handle. The cost for methods to ensure Schedules III through V controlled substance accountability (e.g., perpetual inventory vs. biannual audit and reconciliation) will vary depending on the method chosen by the registrant.

- Classes of persons that will benefit from the proposed rulemaking:

Registrants will benefit from the security and accountability requirements by limiting the opportunity for unauthorized access to the registrant's controlled substances and records, which will limit the opportunity for diversion of controlled substances for illicit purposes. The general public will benefit by having fewer opportunities for the diversion of controlled substances into the general public for illicit purposes.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The cost to a registrant for a two-year registration is $90, which can be prorated if the registration is adjusted to align with the applicant's underlying professional license (individual professional license or business license). The costs for implementation of the security and accountability requirements vary and are at the discretion of the registrant based on the types (schedules) and volume of controlled substances maintained at the registered location.

- Qualitative description of impact:

The proposed requirements will ensure that any supplies of controlled substances maintained at a registered location in this state will be stored securely and that measures will be taken to ensure complete accountability to prevent the unauthorized access to and diversion of controlled and precursor substances and records.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

There are no anticipated implementation costs since the proposed consolidated chapter does not introduce any new requirements to be implemented. The cost to the Board of Pharmacy for enforcement remains the same as under previous regulations.

- Anticipated effect on state revenues:

The effect on state revenues cannot be estimated at this time. Registration fees are deposited into the Licensing and Regulation Fund established by 2023 Iowa Acts, Senate File 557. Registration surcharge fees, if collected, are deposited into the Prescription Monitoring Program Fund in accordance with Iowa Code chapter 124. Only civil penalties assessed as part of a Board disciplinary action are deposited into the State's General Fund.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

As noted above, the costs are widely variable, but the Board believes the minimum requirements for storing and handling controlled substances are justified to prevent the burden and cost of patient harm by ensuring controlled substance security and accountability. The cost of inaction would be increasing the potential for public harm that would continue unchecked without periodic compliance inspections and complaint investigations.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

When attempting to achieve the intended outcome of controlled substance security and accountability to prevent public harm, the Board cannot identify less costly or less intrusive methods. As they relate to Schedules III through V controlled substance accountability measures, the proposed rules provide an option for the registrant to identify an alternative measure preapproved by the Board.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

During the review of existing requirements for storage and handling of controlled substances, the Board did not identify any alternative methods that would be sufficient to prevent unauthorized access to controlled substances or records.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

No alternative methods were identified to be seriously considered for the reason identified above.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

While not specifically identified in this proposed rulemaking, any registrant or permittee is authorized to petition the Board for a waiver of Board rules that are not also required by the Iowa Code (in accordance with 481—Chapter 6). This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules will include information that would demonstrate how the petitioner would continue to protect the public by alternative means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 553:

CHAPTER 553
CONTROLLED AND PRECURSOR SUBSTANCES

481—553.1(124,124B) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

481—553.2(124,124B) General requirements.

553.2(1) *Federal regulations.* Registrants will comply with applicable federal laws and regulations relating to controlled substances, scheduled listed chemical products, and listed chemicals. 21 CFR Chapter 2 as amended September 19, 2023, is incorporated herein by reference.

553.2(2) *Records.*

a. Retention. All records relating to controlled and precursor substances will be maintained at the registered or permitted location for at least two years from the last date of the record or entry to the record.

b. Accessibility. Electronic records will be capable of producing a hard-copy printout of transactions or entries for any specific date or range of dates requested. All records will be available for inspection and copying by the board or its authorized agent.

c. Storage. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited by federal law or regulation. Records maintained in remote storage locations will be retrievable within three business days of a request by the board or its authorized agent.

d. Receipt. In addition to the elements found in 21 CFR §1304.21 and 1304.22, each record of the receipt of controlled substances, including the receipt of complementary packages, will include the signature of the individual responsible for receiving the substances.

e. Dispensing. In addition to the elements found in Iowa Code section 124.306 and 21 CFR §1304.22, each registrant will maintain a record of controlled substances dispensed to a patient or research subject that includes:

(1) The name and NDC number, strength, dosage form, and quantity of the substance dispensed.

(2) The name of the prescriber, unless dispensed by the prescriber.

(3) The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber's agent involved in dispensing.

(4) The serial number or unique identification number of the prescription.

553.2(3) *Inspections.* Pursuant to Iowa Code section 124.302(5), the board may inspect the premises of a registrant, and the inspection may:

a. Be conducted at any time during the registrant's normal operating hours without advance notification to the registrant.

b. Include the review of any record relating to the registered activity.

481—553.3(124,124B) Security. All registrants and permittees will provide effective controls and procedures to guard against theft and diversion of controlled and precursor substances and records. Physical security controls will be commensurate with the schedules and quantity of such substances in the possession of the registrant or permittee in normal business operation and in accordance with 21 CFR Part 1301. The registrant or permittee maintains ultimate responsibility for the accountability of the controlled and precursor substances and records maintained under the registration or permit.

481—553.4(124) Policies and procedures. Each registrant will have policies and procedures that identify, at a minimum:

553.4(1) Adequate storage to ensure security and proper storage conditions in accordance with product package labeling.

553.4(2) Access to controlled substances and records by employees of the registrant.

553.4(3) Proper disposition of controlled substances.

553.4(4) To the extent possible, the separation of duties related to the purchasing, receiving, stocking, dispensing, and reconciling of controlled substance inventory.

553.4(5) The reconciliation of controlled substances in Schedule II pursuant to subrule 553.6(3).

553.4(6) The accountability measures for controlled substances in Schedules III through V pursuant to subrule 553.6(2).

553.4(7) A controlled substance accountability program to document the review of controlled substance inventory adjustments, to review patterns of controlled substance loss, and to create an action plan following a report of theft or loss pursuant to subrule 553.7(3).

481—553.5(124) Physical count and record of inventory. In addition to the inventory requirements found in 21 CFR §1301.52 and 1304.11, each registrant will document a physical count of all on-hand stocks of controlled substances in accordance with 21 CFR §1304.11, except as provided herein.

553.5(1) *Exact quantities.* Each inventory will include the exact count or measure of all controlled substances and may not be an estimated count or measure, except for liquid products packaged in nonincremented containers, which may be estimated to the nearest one-fourth container.

553.5(2) *Annual inventory.* After the initial inventory is taken, a registrant will take a new inventory of all stocks of controlled substances on hand at least annually. The inventory may be taken on any date that is within one year and one week after the date of the previous annual inventory.

553.5(3) *Change of registered location.* An inventory will be taken following the close of business on the last day at the location being vacated that will serve as the ending inventory of the location being vacated as well as the beginning inventory at the new location.

481—553.6(124) Controlled substance accountability. Registrants located in Iowa will ensure accountability of all controlled substances under their control in accordance with this rule.

553.6(1) *Perpetual inventory.* Each registrant will maintain a perpetual inventory that accurately reflects the on-hand inventory of all Schedule II substances at all times. A perpetual inventory may be maintained to accurately reflect the on-hand inventory of all Schedules III through V substances in addition to or in lieu of the measures identified in subrule 553.6(2). The perpetual inventory record will include the following elements, including by supplement or reference, at a minimum, for each substance:

a. Drug name and NDC number.

b. Each receipt and disbursement.

c. Current balance.

d. Incident reports pursuant to subrule 553.6(5).

e. Reconciliation reports pursuant to subrule 553.6(3).

553.6(2) *Accountability measures to ensure accountability of s through V substances.* In lieu of or in addition to a perpetual inventory pursuant to subrule 553.6(1), registrants will utilize one or more of the measures herein to ensure accountability of all Schedules III through V substances under their control.

a. Documented audit and reconciliation of all substances every six months pursuant to paragraph 553.6(3)*"b."*

b. Routine documented cycle counts, so long as all substances are counted every 90 days and reconciled pursuant to paragraph 553.6(3)*"b."*

c. Other measures preapproved by the board.

553.6(3) *Reconciliation.*

a. Perpetual inventory. Individuals responsible for a disbursement will verify that the physical inventory matches the perpetual inventory following each transaction. At least annually, the registrant will verify that the physical inventory matches the perpetual inventory for any substance that was not disbursed in the year. Reconciliation will be documented in the perpetual inventory record to include, at a minimum, the date, the time, the initials or unique identification of the individual, and any discrepancies identified.

b. Schedules III through V reconciliation. In accordance with paragraph 553.6(2)*"b"* or *"c,"* the registrant will verify that the physical inventory matches the expected inventory and will document the reconciliation to include the date, the time, the initials or unique identification of the individual, and any discrepancies identified.

553.6(4) *Discrepancies.* Any discrepancy discovered will be investigated and reported to the registrant or responsible individual immediately but no later than one business day following the discovery. The registrant will determine the need for further investigation, and significant losses will be reported to the board pursuant to rule 481—553.7(124) and to the DEA pursuant to 21 CFR Part 1301.

553.6(5) *Incident reports.* In any instance where a controlled substance inventory record is changed, the individual making the change will complete an incident report to document the change. An electronic record system that documents and maintains the required elements is deemed compliant with this subrule. The report will include, at a minimum, the:

a. Specific information that was changed, including the information before and after the change.

b. Identity of the individual making the change.

c. Date of the change.

d. Detailed explanation for the change.

481—553.7(124) Report of theft or loss—controlled substances. In addition to the notification requirements found in 21 CFR §1301.74 and 1301.76, registrants will submit notice and reports of theft or loss of controlled substances as provided herein.

553.7(1) *Immediate notice to board.* Upon discovery of theft or loss, a registrant will provide immediate notice to the board. The notice will include the identification of the licensee or registrant who is responsible, or believed to be responsible, for the theft or loss, if applicable.

553.7(2) *DEA Form 106 Report of theft or loss.* A copy of the DEA Form 106 or alternate required form will be submitted to the board via facsimile, email attachment, or personal or commercial delivery within 45 calendar days of the discovery of the theft or loss. A copy of the report will be maintained in the registrant's files in accordance with subrule 553.2(2).

553.7(3) *Action plan following loss.* Within seven days following the report of theft or loss, a registrant will develop and initiate implementation of an action plan to address the conditions that contributed to the theft or loss. The action plan will include any directives provided by a board compliance officer, including but not limited to inventory counts, audits, and perpetual inventory counts.

481—553.8(124,124B) Disposal of registrant stock.

553.8(1) *Registrant disposal of controlled substances.*

a. Destruction. Registrants will document disposal of controlled substances pursuant to 21 CFR §1317.95.

b. Administration waste. Registrants will document disposal of controlled substance administration waste pursuant to 21 CFR §1304.22.

553.8(2) *Registrant surrender of controlled substances.* Upon service of a board order suspending or revoking a registration, the registrant will surrender all affected controlled substances in the registrant's possession to the board or its authorized agent. The board or its authorized agent will retain the substances under seal pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for filing an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances may be forfeited to the state.

481—553.9(124) Prescription requirements—valid prescriber/patient relationship. In addition to the elements identified in Iowa Code sections 124.308 and 155A.27 and 21 CFR Parts 1306 and 1311, a prescription is based upon a valid prescriber/patient relationship. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of the controlled substance, a prescription loses its validity. Upon becoming aware of the situation, the pharmacist will cancel the prescription and any remaining refills but may exercise prudent judgment in individual circumstances to ensure sufficient patient access to continued treatment until the patient can reasonably obtain the service of another prescriber.

481—553.10(124) Schedule II prescription changes.

553.10(1) *Changes prohibited.* The following elements may not be added or changed on a Schedule II controlled substance prescription:

a. The patient's name.

b. The substance prescribed, except for generic substitution.

c. The prescriber's name or signature.

553.10(2) *Changes authorized.* Except as prohibited in subrule 553.10(1), elements on a Schedule II controlled substance prescription may be added or amended upon consultation with the prescriber.

481—553.11(124) Dispensing scheduled listed chemical products without a prescription. Pursuant to 21 U.S.C. §830 as amended October 17, 2000, 21 CFR Part 1314, and Iowa Code section 124.212A, registrants will record the retail sales of scheduled listed chemical products. If the real-time electronic pseudoephedrine tracking system (PTS) is unavailable for use, the purchase will be recorded in an alternate format and submitted to the PTS in accordance with subrule 553.11(3).

553.11(1) *Age restriction.* Sales of scheduled listed chemical products are limited to persons aged 18 and older.

553.11(2) *Reporting elements.* In addition to the identified elements in 21 U.S.C. §830, 21 CFR Part 1314, and Iowa Code section 124.212A, the following information will be recorded:

a. The purchaser's current government-issued photo identification number.

b. The total milligrams of the scheduled listed chemical contained in the product.

c. The name or unique identification of the individual who approved the sale.

d. If applicable, the reason that a PTS recommendation to deny the transaction was overridden.

553.11(3) *Alternate record format.* If needed, an alternate record will be maintained using one of the following options:

a. A hard-copy record.

b. A record in the pharmacy's electronic prescription dispensing system that is capable of producing a hard-copy printout of the record.

c. A record in an electronic data collection system that captures each of the required data elements and that is capable of producing a hard-copy printout of the record.

553.11(4) *Delayed submission to the PTS.* Sales of scheduled listed chemical products that are documented in an alternate record due to the inaccessibility of the PTS will be submitted to the PTS within 72 hours of the PTS being accessible, and such record will identify that it is a delayed entry.

481—553.12(124) PTS access. Information collected in the PTS is confidential unless otherwise ordered by a court or released by the governor's office of drug control policy ("office") pursuant to state or federal law. Information may not be released except as provided herein.

553.12(1) *PTS administrators.* PTS administrator access to PTS database information will be pursuant only to reasonable suspicion or an ongoing investigation and only directly from the PTS database. PTS administrators may share PTS database information with law enforcement for purposes of investigation.

553.12(2) *Law enforcement.* Law enforcement officer access to PTS database information will be pursuant to the officer's official duties, which will be provided as part of a request for information from the PTS. Prior to requesting information from the PTS, a law enforcement officer will register with the PTS, which will require verification of the officer's identity and approval by the office or the officer's agency administrator.

553.12(3) *Statistical data.* The PTS administrator, following establishment of confidentiality, may provide summary, statistical, or aggregate data to public or private entities for statistical, research, or educational purposes. Prior to release of any such data, the administrator will remove any personally identifiable information.

553.12(4) *Patients.* A patient may request and receive information regarding products reported to have been purchased by the patient. A request for a patient's purchases and attempted purchases will be submitted to the office located at Oran Pape State Office Building, 215 East 7th Street, Fifth Floor, Des Moines, Iowa 50319, and will include:

a. Patient name, including any aliases used by the patient; date of birth; gender; current address; and daytime phone number.

b. Any address where the patient resided during the requested time period.

c. Current government-issued photo identification, which the PTS administrator will copy and maintain in the PTS records. If the request is submitted other than in person, a copy of the patient's photo identification will be certified by a notary.

d. Patient signature. If the request is submitted other than in person, the patient's signature will be notarized.

553.12(5) *Regulatory agencies.* A regulatory agency may access PTS database information only pursuant to an order, subpoena, or other means of legal compulsion and following submission of a request on a form provided by the office.

553.12(6) *Pharmacy administrators.* A pharmacy or its authorized employees may only access PTS database information relating to the pharmacy's sales, which may be provided to the board upon request of the board or its authorized agent.

553.12(7) *Court orders and subpoenas.* The PTS administrator will provide database information in response to a court order or subpoena issued by a county attorney or a court upon a determination of probable cause.

481—553.13(124,124B) Temporary designation of controlled and precursor substances.

553.13(1) For cannabis-derived products, the board will modify the schedule of controlled substances in accordance with Iowa Code section 124.201A.

553.13(2) Amend Iowa Code section 124.204(2) by adding the following new paragraphs:

cq. 2-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide. Other name: alpha'-Methyl butyryl fentanyl.

cr. N-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-N-phenylpropionamide. Other name: 2',5'-Dimethoxyfentanyl.

cs. N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide. Other name: 3-Furanyl fentanyl.

ct. 3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide. Other name: Isovaleryl fentanyl.

cu. N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide. Other name: meta-Fluorofentanyl.

cv. N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide. Other name: meta-Fluoroisobutyryl fentanyl.

cw. N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide. Other name: ortho-Fluorofuranyl fentanyl.

cx. N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide. Other name: para-Methoxyfuranyl fentanyl.

cy. N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide. Other name: para-Methylcyclopropyl fentanyl.

cz. 1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one. Other name: 2-Methyl AP-237.

553.13(3) Amend Iowa Code section 124.204(4) by adding the following new paragraphs:

cn. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide. Other name: ADB—BUTINACA.

co. 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one. Other name: alpha-PiHP.

cp. 2-(methylamino)-1-(3-methylphenyl)propan-1-one. Other names: 3—MMC; 3-methylmethcathinone.

553.13(4) Amend Iowa Code section 124.204(9) by adding the following new paragraphs:

o. Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate. Other name: MDMB—4en—PINACA.

p. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate. Other names: 4F—MDMB—BUTICA; 4F—MDMB—BICA.

q. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide. Other name: ADB—4en—PINACA.

r. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one. Other names: CUMYL—PEGACLONE; SGT—151.

s. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate. Other names: 5F—EDMB—PICA; 5F—EDMB—2201.

t. Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate. Other name: MMB—FUBICA.

553.13(5) Amend Iowa Code section 124.210(3) by adding the following new paragraphs:

bh. Zuranolone.

481—553.14(124) Excluded and exempt substances.

553.14(1) *Excluded nonnarcotic products.* The board hereby excludes from all schedules the current list of excluded nonnarcotic products identified in 21 CFR §1308.22.

553.14(2) *Exempt substances.* With the exception of listed butalbital products, the board hereby excludes from all schedules the current list of exempted prescription products identified in 21 CFR §1308.32.

481—553.15(124B) Precursor substances—reports. Reports relating to the delivery, receipt, or theft or loss of precursor substances will be in accordance with the requirements identified in Iowa Code chapter 124B and this rule.

553.15(1) *Receipt from out-of-state source.* A report of the receipt of a precursor substance from a source outside the state will be submitted no more than 14 days following such receipt.

553.15(2) *Report elements—receipts and deliveries.* In addition to the elements identified in Iowa Code section 124B.7(1), a report will include the signature of the person or the signature of an officer, authorized agent, or authorized employee of the business receiving or selling, transferring, or furnishing the substance.

553.15(3) *Report elements—theft or loss.* In addition to the elements identified in Iowa Code section 124B.7(1), a report will include the following relating to the missing quantity:

a. The permit number of the reporting person or business.

b. The signature of the reporting person or an officer, authorized agent, or authorized employee of the reporting business.

c. The name and address of the person who transported the substance and the date of the shipment, if applicable.

553.15(4) *Alternative reporting options.* Pursuant to Iowa Code section 124B.7(2), the board may consider requests from permittees to submit reports monthly or via electronic or computer-generated submission.

a. A request to submit transaction reports on a monthly basis or via electronic or computer-generated means will be submitted to the board at least 21 days prior to the board meeting at which the request will be considered.

b. The board will notify the permittee of its decision and identify the reporting format that is authorized. The permittee will be responsible for the accuracy of all reports and the prompt correction of any data entry or transmission errors.

c. Authorization to report monthly or via electronic or computer-generated means is at the board's discretion and may be rescinded with 30 days' advance notice.

553.15(5) *Exemptions.* Reports are not required for the distribution of exempt chemical mixtures or for transactions deemed excluded by 21 CFR Part 1310 as amended October 31, 2023.

481—553.16(124B) Precursor substances—identification of purchaser or other recipient.

553.16(1) *Face-to-face transactions.* In addition to the elements identified in Iowa Code section 124B.3(2)*"c,"* a letter of authorization will include:

a. The name of the purchaser's representative authorized to receive the substance.

b. The signature of the purchaser's representative, completed in the presence of the permittee.

553.16(2) *Non-face-to-face transactions.* Prior to furnishing any precursor substance via a transaction that is not face-to-face, the permittee will require a letter of authorization that includes all of the following:

a. The entity name, address, telephone number, and license number.

b. A description that identifies how the substance will be used.

c. The signature of an officer, authorized agent, or authorized employee of the entity.

d. The typed or printed name and title of the signatory.

These rules are intended to implement Iowa Code section 124.301 and chapter 124B.