

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 2:061: Procedures followed by the Kentucky Board of Pharmacy in the investigation
5 and hearing of complaints.

6 RELATES TO: KRS 218A.205, 315.121, 315.131, 315.191(4), 21 CFR 310.305(b)

7 STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (2), (3), (4)

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to
9 promulgate administrative regulations relating to the practice of pharmacy, including a process
10 for complaints and hearings. KRS 315.191(2) provides the board with the authority to enforce
11 pharmacy laws and regulations. KRS 218A.205(3)(e) (f) and (5) require the board to promulgate
12 administrative regulations relating to complaints, licensure standards, and disciplinary actions.
13 The administrative regulation establishes board procedure for investigations, the administrative
14 hearings process, and the penalties for violations.

15 Section 1. Definitions. (1) “Adverse Drug Experience” means any adverse event associated with
16 the use of a drug in humans, whether or not considered drug related, including the following: an
17 adverse event occurring in the course of the use of a drug product in professional practice; an
18 adverse event occurring from drug overdose, whether accidental or intentional; an adverse event
19 occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of
20 expected pharmacological action;

- 1 (2) “Agreed Order” means a formal written agreement between the board and the licensee,
2 permit holder or registrant that stipulates that a violation of pharmacy law may have occurred
3 and specifies the disciplinary terms and conditions imposed on the licensee, permit holder or
4 registrant.
- 5 (3) “Board” means the Kentucky Board of Pharmacy;
- 6 (4) "Charge" means a specific allegation alleging a violation of a specified provision of this
7 chapter;(5) "Complaint" means a formal administrative pleading that sets forth charges against a
8 licensee, permit holder or registrant and commences a formal disciplinary proceeding;
- 9 (6) “Diversion agreement” means an interim agreement between the board and the licensee,
10 permit holder or registrant that is utilized as a method of ensuring patient safety during a time
11 mutually agreed upon. At the conclusion of the time period, the case review panel may dismiss
12 the grievance, issue a complaint, issue a letter of concern or reprimand, modify the terms of the
13 diversion agreement or enter into an agreed order with the licensee, permit holder or registrant.
- 14 (7) "Executive director" means the executive director of the Kentucky Board of Pharmacy;
- 15 (8) “FDA” means United States Food and Drug Administration;
- 16 (9) “General counsel” means the general counsel of the Kentucky Board of Pharmacy or any
17 attorney hired or contracted with the Kentucky Board of Pharmacy to provide legal services;
- 18 (10) "Grievance" means any allegation in whatever form alleging misconduct by a licensee,
19 permit holder or registrant;
- 20 (11) “Inordinate amount of compounded human drug products” means when a pharmacy has
21 distributed interstate during any calendar year more than fifty percent of the sum of the number
22 of prescription orders for compounded human drug products that the pharmacy sent out of the
23 facility in which the drug products were compounded during that same calendar year plus the

1 number of prescription orders for compounded human drug products that were dispensed at the
2 facility in which they were compounded during that same calendar year;

3 (12) “Letter of concern” means an advisory letter to notify a licensee, permit holder or registrant
4 that, although there is insufficient evidence to support disciplinary action, the board believes the
5 licensee, permit holder or registrant should modify or eliminate certain practices and that the
6 continuation of those practices may result in action against the license, permit or registration;

7 (13) “Letter of reprimand” means a letter admonishing a licensee, permit holder or registrant for
8 violating pharmacy law, but notifying the licensee, permit holder or registrant that in
9 consideration of mitigating evidence, the board has determined that disciplinary action is not
10 appropriate;

11 (14) “Pharmacy Law” means any provision of law in KRS Chapter 315 and 201 KAR Chapter 2
12 or any provision of law in KRS 217 or KRS 218A relating to prescription drugs.

13 (15) “Product quality issue” means any incident that causes the drug product or its labeling to be
14 mistaken for, or applied to, another article, any contamination, any significant chemical,
15 physical, or other change or deterioration in the distributed drug product, or any failure of one or
16 more distributed batches of the drug product to meet the applicable specifications.

17 (16) “Serious adverse drug experience” means any adverse drug experience occurring at any
18 dose that results in death, a life-threatening adverse drug experience, inpatient hospitalization or
19 prolongation of existing hospitalization, a persistent or significant disability of incapacity, or a
20 congenital anomaly or birth defect. Important medical events that may not result in death, be life-
21 threatening, or require hospitalization may be considered a serious adverse drug experience
22 when, based upon appropriate medical judgment, they may jeopardize the patient or subject and
23 may require medical or surgical intervention to prevent one of the above-mentioned outcomes;

1 (17) “Serious product quality issue” means any product quality issue that may have the potential
2 to cause a serious adverse drug experience.

3 Section 2. Grievances (1) A grievance ~~complaint~~ against a licensee may:

4 (a) Be submitted orally or in writing;

5 (b) Originate from a consumer, competitor, health professional, government or provider agency,
6 or other interested party.

7 (2) A grievance ~~complaint~~ shall can be accepted submitted anonymously, and if the grievance
8 ~~complaint~~ is accompanied by sufficient corroborating evidence as ~~would allow the board to~~
9 ~~believe, based upon a totality of the circumstances,~~ that there is a reasonable probability that
10 there has been a violation of pharmacy law, the grievance shall be accepted by the executive
11 director or the general counsel. ~~exists that the complaint is meritorious.~~

12 (3) A grievance ~~complaint~~ shall not be required to be sworn to or notarized.

13 (4) A grievance that alleges adverse drug exposure or a product quality issue from human drug
14 products compounded in Kentucky and distributed outside the state shall be reviewed, and if the
15 grievance is accepted and involves alleged serious adverse drug exposure or serious product
16 quality issue, the grievance shall be reported to the FDA within five (5) business days from
17 receipt of the grievance.

18 (5) A grievance that alleges adverse drug exposure or a product quality issue from a compounded
19 human drug product that was compounded in Kentucky by a physician and distributed outside
20 the state shall be reported to the Kentucky Board of Medical Licensure and the FDA within five

21 (5) business days from receipt of the grievance.

1 Section ~~3~~ 2. Investigations (1) Except as provided by subsection (2) of this section, upon receipt
2 acceptance of a grievance complaint, the executive director board shall instruct its staff or a
3 special investigator to:

4 (a) Conduct an investigation; and

5 (b) ~~Report the conclusions and recommendations of the investigation to the:~~

6 ~~1. Executive director; and~~

7 ~~2. Board member assigned by the board to review conclusions and recommendations relating to~~
8 ~~an investigation. Except as provided by paragraph (d), notify the licensee, permit holder or~~
9 ~~registrant via written letter sent through the United States Postal Service that a grievance has~~
10 ~~been filed, and that the Board is investigating the merits of the grievance. If during the~~
11 ~~investigation, it is alleged that another licensee, permit holder or registrant may have violated~~
12 ~~pharmacy law, that licensee, permit holder or registrant shall also be notified via written letter~~
13 ~~sent through the United States Postal Service that a grievance has been filed and the Board is~~
14 ~~investigating the grievance. Any licensee, permit holder or registrant under investigation shall be~~
15 ~~given the opportunity to provide a written statement to the executive director; and~~

16 (c) Report the case to the case review panel within 120 days of the receipt of the grievance. If an
17 extension of time is requested, the case shall be brought before the case review panel to approve
18 or deny the extension of time. If an extension of time is approved, the licensee, permit holder or
19 registrant that is the subject of the investigation shall be notified via written letter sent through
20 the United States Postal Service of the extension of time. An extension cannot be granted for a
21 period exceeding 120 days. Multiple extensions are permitted; and

22 (d) The executive director may hold an investigation in abeyance for a reasonable period of time
23 or approve of a delay in notice to the licensee, permit holder or registrant in order to permit law

1 enforcement or a government agency to perform or complete essential investigative tasks,
2 following a request by law enforcement or a government agency.

3 (2) If the grievance complaint pertains to the improper, inappropriate, or illegal dispensing of
4 controlled substances, the board shall:

5 (a) File a report with the Attorney General's office, the Office of Inspector General's office, and
6 the Department of the Kentucky State Police within three (3) business days;

7 (b) Commence an investigation within seven (7) days of the grievance complaint; and

8 (c) Produce a charging decision within 120 days of the receipt of the grievance complaint, unless
9 an extension for a definite time period is requested in writing by a law enforcement agency due
10 to an ongoing criminal investigation.

11 (3) If the grievance pertains to human drug products compounded in Kentucky and distributed
12 outside of Kentucky, the investigation shall include assessing whether there is a public health
13 risk associated with the compounded drug product and whether any public health risk associated
14 with the product is adequately contained.

15 (4) A special investigator shall only be utilized when a conflict of interest exists that prevents
16 any board inspector from being assigned to investigate the grievance.

17 Section 43. Case Review Panel (1) A panel consisting of ~~the~~ three assigned board members, ~~the~~
18 ~~executive director, and the pharmacy drug inspector~~ shall review the findings conclusions and
19 ~~recommendation~~ relating to an investigation.

20 (2) Board staff or a special investigator shall provide the written findings and evidence from each
21 investigation to the case review panel, executive director and general counsel at least seven (7)
22 days prior to the meeting of the case review panel.

1 (3) The case review panel shall be empowered to request the attendance of any person, including
2 the assigned inspector, at any meeting of the case review panel in regard to the investigation of
3 any grievance or consideration of any disciplinary matter.

4 (4) The executive director and general counsel shall attend case review panel meetings in a non-
5 voting, ex-officio capacity.

6 (5) The panel shall determine if a preponderance of the evidence exists or does not exist that the
7 licensee, permit holder or registrant violated pharmacy law. If the panel determines that the
8 preponderance of the evidence indicates that the licensee, permit holder or registrant did not
9 violate the law, the case review panel shall dismiss the case with or without prejudice or issue a
10 letter of concern.

11 (6) After reviewing the evidence, if the case review panel determines that a preponderance of the
12 evidence indicates that the licensee, permit holder or registrant violated pharmacy law, the case
13 review panel, shall ~~recommend~~ adopt one (1) of the following dispositions options to the board:

14 (a) Non-adverse action against the licensee, permit holder or registrant. Non-adverse action
15 includes:

16 1. Issuance of a letter of a-reprimand-restricting the licensee, permit or certificate holder; or
17 2. Entry into a diversion agreement.

18 (b) Attempt resolution of the case through an agreed order; or

19 (c) The issuance of a formal complaint, order, and notice of hearing; or

20 (d) Returning the case to the inspector or special investigator for further investigation.

21 (7) (~~3~~) Documentation of a letter of ~~board~~ reprimand, letter of concern or diversion agreement
22 shall be maintained in the appropriate board records files for three years.

1 (8) Within thirty (30) days of the case review panel decision, the licensee, permit holder, or
2 registrant shall be informed via letter sent through the United States Postal Service of the
3 decision of the case review panel.

4 (9) In the case of recusal by a member of the case review panel, the executive director shall
5 replace the recused board member as a voting member of the case review panel.

6 (10) If the case review panel determines by a preponderance of the evidence that a grievance
7 involving human drug products compounded in Kentucky and distributed to another state did
8 violate pharmacy law, the Board shall take action to ensure that the relevant pharmacy
9 investigates the root cause of the problem that is the subject of the grievance and undertakes
10 sufficient corrective action to address any identified public health risk related to the problem,
11 including the risk that future similar problems may occur.

12 ~~Section 4.(1) With the approval of the board, the executive director shall notify the licensee,~~
13 ~~permittee, or certificate holder, in writing, that he or she may request an administrative~~
14 ~~conference before the executive director and the pharmacy drug inspector to be held prior to the~~
15 ~~hearing.~~

16 ~~(2) The licensee, permit or certificate holder shall be notified that he or she may appear with~~
17 ~~counsel. Counsel for the board shall be in attendance as an adviser to the executive director.~~

18 ~~(3) An administrative conference shall be held to determine whether an agreement may be~~
19 ~~reached to resolve the complaint that is acceptable to all parties.~~

20 ~~(4) If an agreement is reached, it shall be submitted to the board for approval and board order.~~

21 Section 5. Settlement (1) At any time after notice of a grievance or the filing of a complaint, a
22 settlement conference may be requested by the licensee, permit or certificate holder, registrant,
23 or the their attorney for that person to resolve a grievance or a complaint.

1 (2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall
2 include the general counsel ~~board's attorney~~, the licensee, permit ~~or certificate~~ holder, registrant,
3 ~~and the attorney for that~~ the licensee, permit holder or registrant person, and anyone else at the
4 request of the licensee, permit holder or registrant.

5 (3) Except as provided in subsection (4), if the parties to a settlement conference agree on
6 stipulations, proposed terms, and conditions for an agreed order to resolve the complaint, they
7 shall forward the agreed order to the board for approval reach an agreement, general counsel,
8 with the consent of the executive director, shall be authorized to resolve the case with a
9 settlement agreement.

10 (4) If the case involves harm to any member of the public, diversion of controlled substances,
11 proposed probation, suspension or revocation, the proposed settlement agreement agreed order is
12 shall be reviewed approved by the case review panel. If the settlement agreement is approved by
13 the case review panel, board, the grievance or complaint shall be considered resolved and a
14 hearing shall not be held.

15 Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS
16 315.131(1) and KRS Chapter 13B.

17 Section 7. Final Order. Post-hearing Proceedings. (1) The board shall deliberate on issuance of a
18 final order on all cases in closed session. Board members that voted on the disposition of the case
19 for the case review panel shall recuse themselves. In the event of board member recusal and the
20 need for a tie-breaking vote, the executive director shall be available to deliberate and vote on
21 issuance of the final order.

22 (2) Board counsel shall not attend, or be involved in any manner with, the closed session.

1 (3) The specific findings of the board shall be made in open session following the board's
2 deliberation.

3 Section 8. Required Penalties For Violations of KRS 218A (1) Pursuant to KRS
4 218A.205(3)(fe)1-, a licensee convicted of a felony offense related to dispensing a controlled
5 substance shall, at a minimum, be permanently banned from dispensing any controlled
6 substance.

7 (2) Pursuant to KRS 218A.205(3)(fe)2-, the board shall impose restrictions short of a permanent
8 ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense
9 relating to the dispensing of a controlled substance.

10 (3) Pursuant to KRS 218A.205(3)(fe)3-, a licensee disciplined by the licensing board of another
11 state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall,
12 at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action
13 imposed by the licensing board of the other state.

14 (4) Pursuant to KRS 218A.205(3)(gf), the board shall submit all disciplinary actions to the
15 National Practitioner Data Bank of the United States Department of Health and Human Services
16 either directly or through a reporting agent.

17 Section 9. Required Reporting of Investigative Findings to the FDA (1) At the conclusion of an
18 investigation of a grievance involving a serious adverse drug experience or a serious product
19 quality issue relating to a drug product compounded at a pharmacy in Kentucky but distributed
20 outside the State, the board shall share, as permitted by state law, the findings of the
21 investigation with the FDA.

22 (2) The Board will maintain records of grievances involving adverse drug experiences or product
23 quality issues relating to human drug products compounded at a pharmacy, the investigations of

1 the grievances, and any response to or action taken as a result of the grievance beginning when
2 the Board receives notice of the grievance. The Board shall maintain these records for at least
3 three (3) years. The three (3) year period begins on the date of final action on a grievance, or the
4 date of a decision that the grievance requires no action.

5 Section 10 Information Sharing with the FDA (1) On an annual basis, the Board shall identify
6 pharmacies that distribute inordinate amounts of compounded human drug products interstate
7 and within thirty (30) days of identifying the pharmacy, notify FDA of such pharmacy.

8 (2) For pharmacies that have been identified as distributing inordinate amounts of compounded
9 human drug products interstate during any calendar year, the Board will identify during the same
10 calendar year:

11 (a) The total number of prescription orders for sterile compounded human drugs distributed
12 interstate; and

13 (b) The names of states in which the pharmacy is licensed; and

14 (c) The names of states into which the pharmacy distributed compounded human drug products;
15 and

16 (d) Whether the state inspected for and found during its most recent inspection that the pharmacy
17 distributed compounded human drug products without valid prescription orders for individually
18 identified patients.

19 (3) If the Board becomes aware of a physician who is distributing any amount of compounded
20 human drug products interstate, the Board shall notify the Kentucky Board of Medical Licensure
21 and within thirty (30) business days of identifying the physician, notify the FDA.



Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

April 13, 2021

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on June 22, 2021 at 1:00 p.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through June 30, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

Contact person: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 2:061.

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: larry.hadley@ky.gov

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes procedures for how the board of pharmacy handles grievances, investigations, review of investigations, disposition of investigations, hearings and the issuance of final orders. This administrative regulation also contains the procedures for handling grievances that involve violations of KRS 218A and compounding violations that have caused adverse drug experiences or presented product quality issues.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary for the Board to be able to protect the safety and health of the citizens of the Commonwealth. This administrative regulation creates procedures for investigating alleged violations of law and the process through which a licensee, permit-holder or registrant could face administrative penalty.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the Board to promulgate administrative regulations to regulate and control all matters pertaining to pharmacists and pharmacies. This administrative regulation provides the procedures through which the Board accepts grievances, conducts investigations and renders decisions when pharmacists or pharmacies have violated the law.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 315.191(1)(a) authorizes the Board to promulgate regulations to allow for the control and regulation of licensees, permit holders and registrants. This administrative regulation provides the processes through which the board is to follow in enforcing the statutes and regulations by which the practice of pharmacy is governed.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: This amendment ensures adequate due process and notice requirements are provided for the licensee, permit holder or registrant to be made aware of any grievance against them, an opportunity to respond, notice of the status of the investigation and notice of the findings of the case review panel in a timely manner. Moreover, this amendment changes the makeup of the case review panel to three members of the board. This amendment removes the administrative conference but bolsters the settlement conference availability. This amendment also creates a settlement process through

which the general counsel and executive director can consent to some settlement agreements for the board. Lastly, this amendment adds language that is required by the board in signing a memorandum of understanding with the FDA to investigate and report to the FDA grievances involving adverse drug experiences and product quality issues from human drug products compounded in the Commonwealth of Kentucky.

- (b) The necessity of the amendment to this administrative regulation: To ensure that licensees, permit holders and registrants are provided sufficient due process, to ensure that there are impartial decision makers to review all cases, and to ensure a process exists for investigating and reporting to the FDA grievances involving adverse drug experiences and product quality issues from human drug products compounded in the Commonwealth of Kentucky.
- (c) How the amendment conforms to the content of the authorizing statutes: KRS 315.002 and 315.005 authorize the board to regulate the practice of pharmacy. KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. This amendment involves the processes through which the board can investigate and dispose of grievances involving potential violations of pharmacy law.
- (d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by providing more robust due process to licensees, permit holders and registrants and by ensuring that an impartial decision maker is determining case outcomes for the board of pharmacy. Moreover, this amendment is ensuring that the public is protected and that the board investigates and reports to the FDA grievances involving adverse drug experiences and product quality issues from human drug products compounded in the Commonwealth of Kentucky.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All licensees, permit holders and registrants with the board will be impacted due to a change in the internal processes the board must follow when accepting grievances, conducting investigations and reviewing cases and rendering final outcomes. This amended regulation affords licensees, permit holders and registrants more due process rights.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: This regulation only impacts actions that the board of pharmacy has to take. It does not create any new rule for a licensee, permit holder or registrant.

- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for compliance with the amendment.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensees, permit holders and registrants will be afforded greater due process rights.
- (5) Provide an estimate of how much it will cost to implement this administrative Regulation:
- (a) Initially: No costs will be incurred.
- (b) On a continuing basis: No costs will be incurred.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this amended regulation.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.
- (9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all licensees, permit holders and registrants.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:061.

Contact Person: Larry Hadley

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1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(a).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the board in subsequent years.

(c) How much will it cost to administer this program for the first year? No increased costs are required to administer this amended regulation for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: