January 24, 2014

HOUSE BILL No. 1218

DIGEST OF HB 1218 (Updated January 21, 2014 9:36 pm - DI 77)

Citations Affected: IC 12-7; IC 12-23; IC 35-48.

Synopsis: Drug treatment and reporting. Requires the division of mental health and addiction (division) to establish standards and protocols for opioid treatment programs to do the following: (1) Assess new opioid treatment program patients to determine the most effective but least addictive opioid treatment drugs to start the patient's opioid treatment. (2) Transition appropriate opioid treatment program patients who are receiving methadone for opioid treatment to less addictive opioid treatment drugs. Allows the division to grant a modification or waiver of the standards and protocols for a patient based on an evaluation and the treatment needs of that patient. Requires an opioid treatment program to follow the standards and protocols adopted by the division for each opioid treatment program patient. Provides a list of the drugs that may be used by an opioid treatment program as a less addictive replacement for methadone. Requires the dispenser at an opioid treatment program to transmit certain information to the division. Provides that the information is subject to federal patient confidentiality regulations. Requires the division to report on the information collected. Increases the penalty to a Level 6 felony for violations of the central repository for controlled substances data laws. Provides that beginning July 1, 2015, the board shall provide for the modification of the controlled substance prescription monitoring program to: (1) accept prescription drug information; and (2) monitor all prescription drugs; in the same manner as controlled substances.
(Continued next page)

Effective: Upon passage; July 1, 2014.

Davisson, Clere

January 14, 2014, read first time and referred to Committee on Public Health.
January 23, 2014, amended, reported — Do Pass.

Digest Continued

Provides that beginning July 1, 2015, any person who is required by the central repository for controlled substances data law to transmit controlled substance information to the INSPECT program must submit all prescription drug information to the INSPECT program in the same manner as controlled substance information is transmitted. Provides that the prescription drug information is confidential and may not be released to a law enforcement officer or law enforcement agency, except for controlled substances. (The introduced version of this bill was prepared by the commission on mental health and addiction.)

January 24, 2014

Second Regular Session 118th General Assembly (2014)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2013 Regular Session and 2013 First Regular Technical Session of the General Assembly.

HOUSE BILL No. 1218

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-7-2-67.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 67.5. "Dispense", for purposes of IC 12-23-18-8, has the meaning set forth in IC 12-23-18-8(a).**

SECTION 2. IC 12-23-18-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 7. (a) The division shall adopt rules under IC 4-22-2 to establish standards and protocols for opioid treatment programs to do the following:**

(1) Assess new opioid treatment program patients to determine the most effective but least addictive opioid treatment drugs to start the patient's opioid treatment.

(2) Have appropriate opioid treatment program patients who are receiving methadone for opioid treatment move to

receiving less addictive opioid treatment drugs.

The division may grant an opioid treatment program a modification or waiver of the standards and protocols for an opioid treatment program patient based on an evaluation and the treatment needs of that patient.

(b) An opioid treatment program shall follow the standards and protocols adopted under subsection (a) for each opioid treatment program patient.

(c) Subject to subsection (a), an opioid treatment program may use any of the following drugs as a less addictive replacement for methadone for opioid treatment:

(1) Buprenorphine.

(2) Buprenorphine combination products containing naloxone.

(3) Any other drug that has been approved by:

(A) the federal Food and Drug Administration for use in the treatment of opioid addiction; and

(B) the division under subsection (e).

(d) Before starting a patient on a new opioid treatment drug, the opioid treatment program shall explain to the patient the potential side effects of the new drug.

(e) The division may adopt rules under IC 4-22-2 to provide for other drugs that are less addictive than methadone that may be used under subsection (a).

SECTION 3. IC 12-23-18-8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 8. (a) As used in this section, "dispense" means to deliver a controlled substance to an ultimate user.**

(b) Subject to the federal patient confidentiality requirements under 42 CFR Part 2, when a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through IC 35-48-2-10 is dispensed at an opioid treatment program, the dispenser shall provide the division with the following information:

(1) An identification number or phrase designated by the division for the controlled substance recipient.

(2) The controlled substance recipient's date of birth.

(3) The national drug code number of the controlled substance dispensed.

(4) The date the controlled substance is dispensed.

(5) The quantity of the controlled substance dispensed.

(6) The number of days of supply dispensed.

(7) The dispenser's United States Drug Enforcement Agency

registration number.

(8) The prescriber's United States Drug Enforcement Agency registration number.

(9) Other data required by the division.

(c) An opioid treatment program is required to provide the information required under this section to the division in a manner prescribed by the division.

(d) The division shall annually report the information collected under this section to the:

(1) commission on mental health and addiction; and

(2) health finance committee.

SECTION 4. IC 35-48-7-8.1, AS AMENDED BY P.L.152-2012, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance is dispensed. **However, notwithstanding any other provision of this section, beginning:**

(A) July 1, 2015, the information required to be transmitted under this section must be transmitted not more than three (3) days after the date on which a controlled substance is dispensed; and

(B) January 1, 2016, the information required to be transmitted under this section must be transmitted not more than twenty-four (24) hours after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 5. IC 35-48-7-11.1, AS AMENDED BY P.L.84-2010, SECTION 99, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 11.1. (a) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality

of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive **controlled substance prescription drug** information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) A controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under IC 25; and

(B) is participating in the assistance program.

(e) Information provided to an individual under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V

controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive ~~the type of~~ **controlled substance prescription drug** information; ~~released;~~ and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

(k) **Except as provided in IC 25-22.5-13,** this section may not be construed to require a practitioner to obtain information about a patient from the data base.

(l) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

SECTION 6. IC 35-48-7-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 14. A person who knowingly or intentionally violates this chapter commits a ~~Class A misdemeanor.~~ **Level 6 felony.**

SECTION 7. IC 35-48-7-16 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 16. (a) Notwithstanding any other provision of this chapter, beginning January 1, 2015, the board shall provide for the modification of the controlled substance prescription monitoring program to:**

(1) accept prescription drug information; and

(2) monitor all prescription drugs;

in the same manner as controlled substances. However, the board

shall take into account that a dispenser does not collect the same information for a noncontrolled substance prescription and a controlled substance prescription, and the board may not require a pharmacy to collect additional information and submit information for a noncontrolled substance prescription unless the information is typically collected by a dispenser.

(b) Notwithstanding any other provision of this chapter, beginning July 1, 2015, any person who is required to transmit controlled substance information to the INSPECT program under this chapter must submit all prescription drug information to the INSPECT program in the same manner as controlled substance information is transmitted.

(c) Notwithstanding any other provision of this chapter, beginning July 1, 2015, the information required to be transmitted under this section must be transmitted not more than three (3) days after the date on which a prescription drug is dispensed.

(d) Notwithstanding any other provision of this chapter, beginning January 1, 2016, the information required to be transmitted under this section must be transmitted not more than twenty-four (24) hours after the date on which a prescription drug is dispensed.

(e) Prescription drug information collected under this section is subject to the confidentiality requirements under section 11.1 of this chapter. However, prescription drug information, except for controlled substances, may not be released to a law enforcement officer or law enforcement agency.

(f) This section does not apply to a facility licensed under IC 16-28 or a hospital licensed under IC 16-21 that is not required to submit prescription information under section 8.1(a)(4) of this chapter.

SECTION 8. **An emergency is declared for this act.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1218, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 3, delete lines 12 through 42, begin a new paragraph and insert:

"SECTION 4. IC 35-48-7-8.1, AS AMENDED BY P.L.152-2012, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance is dispensed. **However, notwithstanding any other provision of this section, beginning:**

(A) July 1, 2015, the information required to be transmitted under this section must be transmitted not more than three (3) days after the date on which a controlled substance is dispensed; and

(B) January 1, 2016, the information required to be transmitted under this section must be transmitted not more than twenty-four (24) hours after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 5. IC 35-48-7-11.1, AS AMENDED BY P.L.84-2010, SECTION 99, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 11.1. (a) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving,

processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive **controlled substance prescription drug** information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) A controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under IC 25; and

(B) is participating in the assistance program.

(e) Information provided to an individual under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive ~~the type of~~ **controlled substance prescription drug** information; ~~released;~~ and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information

that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

(k) **Except as provided in IC 25-22.5-13,** this section may not be construed to require a practitioner to obtain information about a patient from the data base.

(l) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith."

Page 4, delete lines 1 through 13, begin a new paragraph and insert:

"SECTION 6. IC 35-48-7-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 14. A person who knowingly or intentionally violates this chapter commits a ~~Class A misdemeanor.~~ **Level 6 felony.**".

Page 4, line 22, after "substances." insert "**However, the board shall take into account that a dispenser does not collect the same information for a noncontrolled substance prescription and a controlled substance prescription, and the board may not require a pharmacy to collect additional information and submit information for a noncontrolled substance prescription unless the information is typically collected by a dispenser.**".

Page 4, line 24, delete "January" and insert "**July**".

Page 4, between lines 28 and 29, begin a new paragraph and insert:

"**(c) Notwithstanding any other provision of this chapter, beginning July 1, 2015, the information required to be transmitted under this section must be transmitted not more than three (3)**

days after the date on which a prescription drug is dispensed.

(d) Notwithstanding any other provision of this chapter, beginning January 1, 2016, the information required to be transmitted under this section must be transmitted not more than twenty-four (24) hours after the date on which a prescription drug is dispensed.".

Page 4, line 29, delete "(c)" and insert "**(e)**".

Page 4, between lines 33 and 34, begin a new paragraph and insert:

"**(f) This section does not apply to a facility licensed under IC 16-28 or a hospital licensed under IC 16-21 that is not required to submit prescription information under section 8.1(a)(4) of this chapter.**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1218 as introduced.)

CLERE, Chair

Committee Vote: yeas 10, nays 0.