SECOND REGULAR SESSION

SENATE BILL NO. 544

96TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR CHAPPELLE-NADAL.

Pre-filed December 9, 2011, and ordered printed.

4109S.01I

TERRY L. SPIELER, Secretary.

AN ACT

To amend chapter 324, RSMo, by adding thereto sixteen new sections relating to the licensing of clinical laboratory science personnel, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 324, RSMo, is amended by adding thereto sixteen new

- 2 sections, to be known as sections 324.1300, 324.1303, 324.1306, 324.1309,
- $3 \quad 324.1312, 324.1315, 324.1318, 324.1321, 324.1324, 324.1326, 324.1328, 324.1332,$
- 4 324.1334, 324.1336, 324.1338, and 324.1340 to read as follows:

324.1300. Sections 324.1300 to 324.1340 shall be known and may

2 be cited as the "Clinical Laboratory Science Practice Act".

324.1303. As used in sections 324.1300 to 324.1340, the following

- 2 terms, unless otherwise indicated within the context, shall mean:
- 3 (1) "Approved national certification examination", a competency
- 4 based certification examination that is administered by a national non-
- profit credentialing agency and is approved by the board;
- 6 (2) "Board", the Missouri clinical laboratory science board
 - appointed by the governor;
- 8 (3) "Categorical laboratory scientist", an individual eligible under
- 9 sections 324.1300 to 324.1340 to perform the functions of a medical
- 10 laboratory scientist limited under the individual's license to one or
- 11 more categories of laboratory testing, such as microbiology, virology,
- 12 clinical chemistry, immunology, hematology, immunohematology,
- 13 molecular diagnostics, cytogenetics, stem cell processing, electron
- 14 microscopy, histocompatability, cellular immunology, flow cytometry,
- 15 or other areas specified by the board, under the supervision, control
- 16 responsibility, and direction of the laboratory director;

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- 17 (4) "CLIA", refers to the final regulations promulgated by the 18 United States Department of Health and Human Services implementing 19 the Clinical Laboratory Improvement Amendments of 1988, P.L. 100-578 20 and 42 CFR 493;
- 21(5) "Clinical laboratory" or "laboratory", any site or location in 22 which clinical laboratory tests or examinations are performed;
- 23 (6) "Clinical laboratory test", a microbiological, serological, molecular, chemical, biological, hematological, immunological, 2425 immunohematological, cytogenetics, stem cell processing, electron microscopy, histocompatability, cellular immunology, flow cytometry, 26 27or any other test or procedure performed on material derived from or present within a human body which provides information for 28diagnosing, preventing, or monitoring treatment of a clinical 29condition. Clinical laboratory testing encompasses the pre-analytical, 30 analytical, and post-analytical phases of testing; 31
- 32 (7) "Department", the department of insurance, financial institutions and professional registration; 33
- 34 (8) "Director", the director of the division of professional 35 registration;
- (9) "Independent technical judgment", the performance or conduct of clinical laboratory tests and assumption of responsibility for determination of the validity of clinical laboratory test results without 38 39 intervention by, or the supervision of, another health care provider authorized by law to assume responsibility for the conduct and validity 40 of clinical laboratory tests. The authorized exercise of independent 41 technical judgment, as it pertains to clinical laboratory personnel, shall 42not be deemed to include or permit the exercise of independent medical judgment in diagnosing or treating patients, except as authorized in 44accordance with CLIA;
 - (10) "Laboratory director", an individual eligible under CLIA to direct a clinical laboratory;
- (11) "Medical laboratory scientist", an individual eligible under 48 sections 324.1300 to 324.1340, to perform any clinical laboratory test, 49 including those that require the exercise of independent technical judgment, subject to the supervision, control, responsibility, and 51direction of the laboratory director. In addition, this individual is 52responsible for, with oversight by the laboratory director, the 53

establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the pre-analytic, analytic, and post-analytic phases of testing. The medical laboratory scientist may also direct, supervise, consult, educate, and perform research functions;

- (12) "Medical laboratory technician", an individual eligible under sections 324.1300 to 324.1340, who is qualified to perform clinical laboratory tests in accordance with established and approved protocols with oversight from a medical laboratory scientist, and under the supervision, control, responsibility, and direction of the laboratory director;
- (13) "Phlebotomist", an individual responsible for obtaining a blood specimen by venipuncture or capillary puncture according to established and approved protocols and also qualified to perform waived or point-of-care testing under the direction of a medical laboratory scientist, clinical laboratory technician, laboratory supervisor, or laboratory director;
- (14) "Point-of-care testing", clinical laboratory testing that is critical to patient care and must be performed immediately at the patient's location. Tests which meet this definition provide clinically relevant information which determines the patient's therapy, are limited to procedures that produce accurate data within a short period of time, meet the current standards of quality in clinical laboratory science, and comply with all standards of accrediting agencies. Point-of-care testing shall be under the direction, authority, jurisdiction, and responsibility of a person licensed under sections 324.1300 to 324.1340;
- (15) "Temporary license", a license issued to an applicant eligible to sit for, and registered to take, an approved national certification examination, or who has taken the examination and is awaiting the results, or an applicant who meets the educational requirements for the license and is seeking to qualify for the certification examination by completing the supervised clinical laboratory experience requirements;
- (16) "Trainee", an individual who is working towards, but has not fulfilled the educational or training requirements under sections 324.1300 to 324.1340, or necessary to qualify to take an approved nationally recognized certification examination, if such examination is required;

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91 (17) "Waived", "provider performed microscopy", "moderate 92 complexity", and "high complexity", the categories of clinical laboratory 93 test complexity as defined by CLIA.

324.1306. Sections 324.1300 to 324.1340 do not apply to:

- 2 (1) Licensed health care professionals whose scope of practice 3 includes blood collection or the performance of waived or provider 4 performed microscopy testing as defined by CLIA;
- 5 (2) Individuals holding a doctorate in chemical, physical, or 6 biological sciences or medicine and board certified as defined by CLIA;
- 7 (3) Clinical laboratory practitioners employed by the United 8 States government or any bureau, division, or agency thereof, while in 9 the discharge of the employee's official duties;
 - (4) Clinical laboratory science professionals engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease;
- 13 (5) Students or trainees enrolled in an accredited clinical laboratory science education program, provided that their activities constitute a part of a planned course in the program, that the individuals are designated by title as trainee or student, and that the individuals work under the direct supervision of a duly licensed clinical laboratory practitioner who is responsible for reporting test results;
- 20 (6) Individuals performing only waived testing in an institution 21 meeting current CLIA regulations;
 - (7) A licensed physician or laboratory director; and
- 23 (8) Pathologist assistants, histotechnologists, histotechnicians, 24 and cytotechnologists that are qualified or otherwise allowed to 25 perform these functions in accordance with CLIA, provided that 26 nothing in sections 324.1300 to 324.1340 shall be construed as a 27 limitation on the scope of work permitted under CLIA for qualified cytotechnologists.

324.1309. 1. Any person who holds a license under sections 324.1300 to 324.1340 may use the titles "medical laboratory scientist", "categorical laboratory scientist", "medical laboratory technician", or "phlebotomist". No other person may use such titles or shall assume any title or use any abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is a medical

7 laboratory scientist, categorical laboratory scientist, medical 8 laboratory technician, or a phlebotomist.

2. No person shall practice or offer to practice within the scope of practice of licensees under sections 324.1300 to 324.1340 for compensation or use any title, sign, abbreviation, card, or device to indicate that such person is practicing unless he or she has been duly licensed under the provisions of sections 324.1300 to 324.1340.

324.1312. 1. There is hereby created within the division of professional registration, the "Clinical Laboratory Science Board" which shall guide, advise, and make recommendations to the division and fulfill other responsibilities designated by sections 324.1300 to 324.1340. The board shall approve the examinations required by, and shall assist the division in carrying out the provisions of, sections 324.1300 to 324.1340.

8 2. The board shall consist of nine members, including one public member, appointed by the governor with the advice and consent of the 9 10 senate. Each member of the board shall be a citizen of the United 11 States, a resident of this state for at least one year and a registered 12voter. Except for the public member, board membership shall consist 13 of two physicians who are laboratory directors, one non-physician 14 laboratory director, three medical laboratory scientists, and two medical laboratory technicians. Members shall serve on the board until 15 16 a successor is appointed by the governor. The membership of the board shall reflect the differences in work experience and levels of education 17 with consideration being given to race, gender, and ethnic origins. 18

3. Beginning with the appointments made after August 28, 2012, three members shall be appointed for four years, three members shall be appointed for three years, and three members shall be appointed for two years. Thereafter, all members shall be appointed to serve four-year terms.

4. A vacancy in the office of a member shall be filled by appointment by the governor for the remainder of the unexpired term.

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5. The board shall hold an annual meeting at which it shall elect from its membership a chairperson and vice chairperson. The board may hold such additional meetings as may be required in the performance of its duties. A quorum of the board shall consist of a majority of its members.

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6. The governor may remove a board member for misconduct, incompetence or neglect of official duties after giving the board 33 member written notice of the charges and allowing the board member an opportunity to be heard. Members can also be terminated for the 34following reasons: change of legal residence by moving out of the state; missing three consecutive meetings; or having their professional license revoked or suspended.

7. The public member shall at the time of appointment, not have been a member of any profession licensed or regulated under sections 324.1300 to 324.1340 or an immediate family member of such a person; and may not have had a material financial interest in either the providing of any service governed by sections 324.1300 to 324.1340 or in an activity or organization directly related to any profession licensed or regulated by sections 324.1300 to 324.1340. The duties of the public member shall not include any determination of the technical requirements to be met for licensure, whether a candidate for licensure meets such technical requirements, or of the technical competence or technical judgment of a licensee or a candidate for licensure.

8. Notwithstanding any other provision of law to the contrary, any appointed member of the board shall receive as compensation an amount established by the director of the division of professional registration not to exceed seventy dollars per day for commission business plus actual and necessary expenses.

9. The board shall keep records of its official acts, and certified copies of any such records attested by a designee of the board shall be received as evidence in all courts to the same extent as the board's original records would be received.

10. All funds received by the board under the provisions of sections 324.1300 to 324.1340 shall be collected by the director who shall transmit the funds to the department of revenue for deposit in the state treasury to the credit of the "Clinical Laboratory Science Fund" which is hereby created. The state treasurer shall be custodian of the fund and may approve disbursements from the fund in accordance with sections 30.170 and 30.180. Upon appropriation, money in the fund shall be used solely for the administration of sections 324.1300 to 324.1340. Notwithstanding the provisions of section 33.080 to the contrary, money in this fund shall not be transferred and placed to the

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credit of general revenue until the amount in the fund at the end of the biennium exceeds three times the amount of the appropriation from the fund for the preceding fiscal year. The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

324.1315. 1. The board is authorized to promulgate rules and regulations regarding:

- (1) The content of license applications and the procedures for filing an application for an initial or renewal license in this state;
- 5 (2) The content, conduct, and administration of the licensing 6 examinations required by sections 324.1300 to 324.1340;
- 7 (3) Educational or experience requirements for licensure only to 8 the extent that sections 324.1300 to 324.1340 expressly provides for 9 board adoption of such requirements;
- 10 (4) The standards and methods to be used in assessing
 11 competency as a medical laboratory scientist, categorical laboratory
 12 scientist, medical laboratory technician, or a phlebotomist only to the
 13 extent that sections 324.1300 to 324.1340 expressly provides for board
 14 adoption of such standards and methods;
- 15 (5) All applicable fees, set at a level to produce revenue which 16 shall not exceed the cost and expense of administering the provisions 17 of sections 324.1300 to 324.1340;
- 18 (6) Establishment of procedures for granting reciprocity with 19 other states.
- 20 2. Any rule or portion of a rule, as that term is defined in section 21536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This 23 section and chapter 536, are nonseverable and if any of the powers 24vested with the general assembly under chapter 536 to review, to delay 2526 the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any 2728rule proposed or adopted after August 28, 2012, shall be invalid and 29 void.

324.1318. The division shall:

(1) Employ, within the funds appropriated, any such employees,

3 as defined in section 620.010 that are necessary to carry out the 4 provisions of sections 324.1300 to 324.1340; and

- 5 (2) Exercise all budgeting, purchasing, reporting, and other 6 related management functions.
- 324.1321. 1. Any applicant for a license under sections 324.1300 to 324.1340 shall authorize the board to conduct a criminal background check.
- 4 2. The cost of such background check shall be paid by the 5 applicant.
- 324.1324. 1. Applications for licensure as a medical laboratory scientist, categorical laboratory scientist, medical laboratory technician, and phlebotomist shall be in writing, submitted on forms prescribed by the board and furnished to the applicant. Each application shall contain a statement that it is made under oath or affirmation and that the information contained therein is true and correct to the best knowledge and belief of the applicant, subject to the penalties provided for the making of a false affidavit or declaration. Each application shall be accompanied by the fees required by the board.
- 2. An applicant for licensure under subsection 1 of this section 12 shall be at least eighteen years of age.
- 3. Each applicant shall furnish evidence to the board of the applicant's education, experience, and such other information as the board may require.
- 4. Licenses shall be awarded to applicants as follows:
- (1) The board shall issue a medical laboratory scientist's license to an individual who possesses a baccalaureate degree from a regionally accredited college or university, has acceptable clinical laboratory experience or training, and passes a nationally recognized certification examination authorized by the board;
- (2) The board shall issue a categorical laboratory scientist's license to an individual who possesses a baccalaureate degree from a regionally accredited college or university, has acceptable clinical laboratory experience or training, and passes a nationally recognized certification examination in a recognized discipline of laboratory science authorized by the board, if such a certification examination exists for that discipline. The laboratory discipline will be specified on

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- (3) The board shall issue a medical laboratory technician's license to an individual who possesses an associate degree from a regionally accredited college or university, has acceptable laboratory experience or training or equivalent training and experience in the United States armed forces, and passes a nationally recognized certification examination authorized by the board;
 - (4) The board shall issue a phlebotomist's license to an individual who possesses a high school diploma or equivalent, has acceptable experience or training, and passes a nationally recognized certification examination authorized by the board.
- 5. The board shall issue a temporary license to practice without 40 examination to an applicant who has duly become licensed in any 41 profession to practice within the scope of practice of licensees under 42sections 324.1300 to 324.1340 pursuant to the laws of another state, 43 territory, or foreign country, if the applicant meets the qualifications 44 required of such licensee in this state at the time the applicant was 45 46 originally licensed in the other state, territory, or foreign country. Temporary licenses may be issued to an applicant who is 4748 eligible to sit for and registered to take the next scheduled certification 49 examination, who has taken the examination and is awaiting the results, or who is seeking to qualify for the certification examination 50 51 by completing the supervised clinical laboratory experience required 52 if the applicant meets the education requirements for licensure.
- 2 laboratory specimens, performing, or reporting laboratory tests or consulting regarding clinical laboratory tests, or currently practicing as clinical laboratory practitioners on December 26, 2012, who are certified by or eligible for certification by an agency acceptable to the board, and who have applied to the board on or before December 26, 2012, and have complied with all necessary requirements for such application may continue to perform the duties until the expiration of twelve months after the filing of such application, the denial of the application by the board, or the withdrawal of the application, whichever occurs first.
- 2. Persons not meeting the education, training, and experience qualifications for any license described in sections 324.1300 to 324.1332

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prior to August 28, 2014, shall be considered to have met the qualifications provided they have three years of acceptable experience at the professional level for which licensure is sought during the five-year period immediately prior to August 28, 2012, and submit to the board the job description of the position which the applicant has most recently performed, attested to by his or her employer. The board shall determine the type of license for which the applicant is eligible.

3. Effective August 28, 2014, no initial license shall be issued until an applicant meets all of the requirements under sections 324.1300 to 324.1340 and successfully passes a board approved certification examination. This section does not apply to temporary licenses.

324.1328. 1. The division shall mail a renewal notice to the last known address of each licensee prior to the renewal date. Failure to receive this notice does not relieve the licensee of the obligation to renew the license to practice.

2. A new license to replace any license lost, destroyed, or mutilated may be issued subject to the rules of the board upon payment of a fee.

324.1332. 1. A licensee may ask to be put on inactive status, provided such person does not practice during such period that the practitioner is on inactive status. If the person desires to maintain such license on an inactive status and in order to avoid lapsing of such license, the person shall pay the required fee as established by the board for maintaining an inactive license. An inactive license shall be renewed biennially. An inactive license may be reactivated by the board as provided by rule.

2. Any person who practices as a medical laboratory scientist, categorical laboratory scientist, medical laboratory technician, or a phlebotomist during the time his or her license is inactive or lapsed shall be considered an illegal practitioner and shall be subject to the penalties for violation of sections 324.1300 to 324.1340.

324.1334. 1. The board may refuse to issue any license or renew any license required by the provisions of sections 324.1300 to 324.1340 for one or any combination of reasons stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of the right to file a complaint with the administrative hearing commission as provided in

- 7 chapter 621.
- 8 2. The board may cause a complaint to be filed with the
- 9 administrative hearing commission as provided in chapter 621 against
- 10 the holder of any license required by sections 324.1300 to 324.1340 or
- 11 any person who has failed to renew or has surrendered the person's
- 12 license for anyone or any combination of the following causes:
- 13 (1) Use of fraud, deception, misrepresentation, or bribery in
- 14 securing a license issued pursuant to the provisions of sections
- 15 **324.1300** to **324.1340**;
- 16 (2) Impersonation of any person holding a license or allowing
- 17 any person to use his or her license or diploma from any school;
- 18 (3) Disciplinary action against the holder of a license or other
- 19 right to practice any profession within the scope of practice of
- 20 licensees under sections 324.1300 to 324.1340 by another state, territory,
- 21 federal agency or country upon grounds for which revocation or
- 22 suspension is authorized in this state;
- 23 (4) Issuance of a license based upon a material mistake of fact;
- 24 (5) The person has committed any criminal offense, whether or
- 25 not a criminal charge has been filed:
- 26 (a) For any offense committed during the course of the practice
- 27 of the profession;
- 28 (b) For any offense reasonably related to the qualifications,
- 29 functions, or duties of the profession;
- 30 (c) For any offense an essential element of which is fraud,
- 31 dishonesty, or act of violence; or
- 32 (d) For any offense involving moral turpitude;
- 33 (6) Incompetence, misconduct, fraud, misrepresentation, or
- 34 dishonesty in the performance of the functions or duties of the
- 35 profession that is regulated by sections 324.1300 to 324.1340;
- 36 (7) Violation of, or assisting or enabling any person to violate,
- 37 any provision of sections 324.1300 to 324.1340, or any lawful rule or
- 38 regulation adopted under such sections;
- 39 (8) A person is finally adjudged insane or incompetent by a court
- 40 of competent jurisdiction;
- 41 (9) Use of any advertisement or solicitation that is false,
- 42 misleading, or deceptive to the general public or persons to whom the
- 43 advertisement or solicitation is primarily directed;

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(10) Obtaining or attempting to obtain any fee, charge, tuition, 44 45 or other compensation by fraud, deception, or misrepresentation;

- 46 (11) Unlawful use or unlawful possession of any controlled substance, as defined in chapter 195, or use of alcoholic beverages to 47 an extent that such use impairs a person's ability to perform the work 48 of any profession that is licensed or regulated by sections 324.1300 to 324.1340;
- 51 (12) Violation of any professional trust or confidence;
- 52 (13) Failing, within sixty days, to provide information in response to a written request made by the board; 53
- (14) Directly or indirectly, giving to or receiving from, any 54 person, firm, corporation, partnership, or association any fee, 55commission, rebate, or other form of compensation for any professional 56services not actually rendered; 57
- 58 (15) Willfully making or filing false records or reports in his or 59 her practice, including but not limited to, false records filed with state agencies or departments; 60
- 61 (16) Engaging in dishonorable, unethical, or unprofessional 62 conduct of a character likely to deceive, defraud, or harm the public;
- 63 (17) Directly or indirectly contracting to perform clinical laboratory tests in a manner which offers or implies an offer of rebate or fee-splitting inducements or arrangements. 65
 - 3. Any person, organization, association, or corporation who reports or provides information to the board in compliance with the provisions of sections 324.1300 to 324.1340 and who does so in good faith shall not be subject to an action for civil damages as a result thereof.
- 4. After the filing of a complaint under subsection 2 of this 71section, the proceedings shall be conducted in accordance with the 7273 provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this 74section, for disciplinary action are met, the board may, singly or in 75combination, censure or place the person named in the complaint on 76probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for 78a period not to exceed three years, or revoke the license of the person. 79An individual whose license has been revoked shall wait three years 80

81 from the date of revocation to apply for relicensure. Relicensure shall

- 82 be at the discretion of the board after compliance with all requirements
- 83 of sections 324.1300 to 324.1340 relative to the licensing of an applicant
- 84 for the first time.
- 5. The board shall maintain an information file containing each
- 86 complaint filed with the board relating to a holder of a license.
- 6. The board shall recommend for prosecution violations of
- 88 sections 324.1300 to 324.1340 to an appropriate prosecuting or circuit
- 89 attorney.
 - 324.1336. 1. Upon proper application by the board, a court of
 - 2 competent jurisdiction may grant an injunction, restraining order, or
- 3 other order as may be appropriate to enjoin a person from:
- 4 (1) Offering to engage or engaging in the performance of any acts
- 5 or practices for which a certificate of registration or authority, permit
- 6 or license is required by sections 324.1300 to 324.1340 upon a showing
- 7 that such acts or practices were performed or offered to be performed
- 8 without a certificate of registration or authority, permit, or license; or
- 9 (2) Engaging in any practice or business authorized by a
- 10 certificate of registration or authority, permit, or license issued under
- 11 sections 324.1300 to 324.1340 upon a showing that the holder presents
- 12 a probability of serious danger to the health, safety, or welfare of any
- 13 resident of the state or client or patient.
- 2. Any such actions shall be commenced either in the county in
- 15 which such conduct occurred or in the county in which defendant
- 16 resides.
- 3. Any action brought under this section shall be in addition and
- 18 not in lieu of any penalty provided by law and may be brought
- 19 concurrently with other actions to enforce sections 324.1300 to 324.1340.
 - 324.1338. Any person who violates any provision of sections
- 2 324.1300 to 324.1340 shall be guilty of a class A misdemeanor.
- 324.1340. 1. The chairperson of the board may administer oaths,
- issue subpoenas duces tecum, and require production of documents and
- s records. Subpoenas duces tecum shall be served by a person
- 4 authorized to serve subpoenas of courts of record. In lieu of requiring
- 5 attendance of a person to produce original documents in response to a
- 6 subpoena duces tecum, the board may require sworn copies of such
- 7 documents to be filed with it or delivered to its designated

8 representative.

9 2. The board may enforce its subpoenas duces tecum by applying to a circuit court of Cole County, the county of the investigation, hearing or proceeding, or any county where the person resides or may be found, for an order upon any person who shall fail to comply with 12 a subpoena duces tecum to show cause why such subpoena should not 13 be enforced, which such order and a copy of the application therefore 14 shall be served upon the person in the same manner as a summons in 15a civil action, and if the circuit court shall, after a hearing, determine 16 that the subpoena duces tecum should be sustained and enforced, such 1718 court shall proceed to enforce the subpoena duces tecum in the same manner as though the subpoena duces tecum had been issued in a civil 19 case in the circuit court. 20

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