

SHINGLE SPRINGS HEALTH AND WELLNESS CENTER PHARMACY

POLICIES AND PROCEDURES MANUAL

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SECTION 1: PREFACE

(A) Purpose

This manual shall state Shingle Springs Health and Wellness Center Pharmacy policies and set forth operational procedures. All pharmacy employees must become familiar with SSHWCPh Policies and may refer to this manual as needed. Additionally, this manual is a teaching tool to acquaint employees with the SSHWCPh operation. Compliance with these policies and procedures is a condition of employment and noncompliance may lead to termination. When unaddressed issues arise, remember to prioritize the patients' needs first, and to uphold the respect of the Community Pharmacy, Health & Wellness Center, Shingle Springs Band of Miwok Indians, and all applicable laws.

(B) Mission Statement

Shingle Springs Health and Wellness Center Pharmacy and its staff strive to offer Tribal Members, customers and patient's comprehensive pharmacy services in a professional and friendly setting. All individuals are treated with respect and dignity without regard to race, religion, economic status, gender, age or sexual orientation. The Pharmacy and staff puts the patients' needs and concerns as its top priority.

(C) Scope of Practice

Shingle Springs Community Health and Wellness Center Pharmacy is a full service, tribally operated pharmacy. This pharmacy's purpose is to provide comprehensive pharmacy service to members of the *Shingle Springs Band of Miwok Indians*, and private customers in our area. In addition to maintaining a well-stocked pharmacy department, *Shingle Springs Community Health and Wellness Center Pharmacy* provides a useful selection of OTC (Over the Counter) supplies at competitive pricing. Customers may frequent the pharmacy or have purchases delivered or mailed for their convenience.

(D) Policy Review

No less than annually shall this manual be reviewed for the timeliness and appropriateness of content. A notation shall be made on the appropriate page by the reviewing pharmacist as to the date the policy was reviewed and any changes made to the policy. Occasionally a complete revision may occur, and a new manual with a new version number (i.e. v X.2) will be created. Additions shall be dated as they are added to the manual. The Pharmacy Director is responsible for reviewing this manual. Any changes must be approved by the Clinic Manager, The Shingle Springs Health and Wellness Center Health Board and the Shingle Springs Band of Miwok Indians Tribal Council. All Shingle Springs Health and Wellness Center policies apply to any employee working in the SSHWC pharmacy. If at any point the two policies conflict, the SSHWC policies will supercede.

(E) Policy Notification by Memo

New or changed policies may be issued by memo, posted in a common place for staff to read. After reading, each employee shall initial and date where indicated. Dated, acknowledged memos will be retained in the appendix of this manual for incorporation in future revisions.

(F) Pharmacy Details

**Shingle Springs Health and Wellness
Center Pharmacy**

5168 Honpie Road
5th Floor
Placerville, CA 95667
(530) 387-8215
(530) 676-4416 fax

Pharmacy License: CA PHY55274
DEA number: FS6531948
NCPDP: 5662083
NPI number: 1710423793

Pharmacist in Charge:
John Bodtker, PharmD

(G) Pharmacy Staff & Contact List

	Name	Phone	License
Pharmacy Director	John D. Bodtker	(530) 387-8005	CA RPH-62197
Pharmacist in Charge	John D. Bodtker	(530) 387-8005	CA RPH-62197
Pharmacist			
Pharmacist			
Technician			
Technician			
Clerk			
Clerk			

(H) Pharmacist in Charge

The pharmacy must have a ‘Pharmacist in Charge’ identified and registered with the State Board of Pharmacy. The PIC is responsible for the daily operation of the pharmacy, and has full authority to assure the pharmacy’s compliance with all laws governing Pharmacy operation. Any change of PIC must be reported by to the pharmacy board, using appropriate documentation, within 30 days.

SECTION 2: ADMINISTRATION POLICIES

(A) Drug Free Workplace

Shingle Springs Health and Wellness Center Pharmacy is a drug-free work environment.

(B) Impairment and Diversion Policy

The pharmacy must take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. In such an event, the individual must be immediately dismissed pending investigation.

The pharmacy must report to the pharmacy board within 14 days of the receipt or development of information with regard to any licensed individual employed by or with the pharmacy:

- i. Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice
- ii. Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs
- iii. Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice
- iv. Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual
- v. Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice
- vi. Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs

The pharmacist in charge will immediately report any of the above to the Clinic Manager.

(C) Absence of Pharmacist

During the temporary absence of the pharmacist for breaks or meal periods, including authorized duties of personnel, the pharmacist is responsible for checking all work performed by ancillary staff during the absence.

Orders for controlled drugs or those that require consultation must not be dispensed without a pharmacist immediately available.

Regardless, it remains the Pharmacist's responsibility for maintaining the security of the pharmacy thus if the Pharmacist on duty must be out of the pharmacy for any reason the Pharmacy Director will take his/her place until they return.

(D) Annual Self-Assessment and Inventory

The [*Community Pharmacy Self-Assessment\(link\)*](#) document is available at www.pharmacy.ca.gov

The State Board of Pharmacy requires biennial a biennial pharmacy self-assessment before July 1 of each odd numbered year.

A self-assessment must be completed within 30 days if a new permit is issued or a new PIC employed.

Shingle Springs Community Health and Wellness Center Pharmacy shall complete a full self-assessment and inventory audit annually.

Self-assessment shall be available for review for at least three years.

(E) Quality Assurance Program

The pharmacy Quality Assurance binder shall be readily retrievable, and contain associated documents. The quality assurance program documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. Pharmacy quality assurance policies and procedures are maintained in the QA binder and are immediately retrievable and maintained in the pharmacy for at least one year from the date it was created.

The pharmacist will notify the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. When a medication error has occurred and

the drug was administered to or by the patient, or resulted in a clinically significant delay in therapy the pharmacist must notify the prescriber of the error has occurred. Investigation of pharmacy medication errors must be initiated within two business days from the date discovered.

An Incident Report (See Form 'Incident Report: Quality Assurance Binder' in Appendix) for a medication error contains:

Date, location, and participants; pertinent data and other information related to the error reviewed; findings and determinations; and recommended changes to pharmacy policy, procedure, systems or processes, if any.

(F) Posting of Licenses and Notices

Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)

The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status.

(G) Records

Completed pharmacy self –assessments must remain on file for three years in the Staff Training Binders.

All drug acquisition and disposition records are maintained for at least three years, SSHWCPH will maintain these records for 5 years.

These records include:

- i. Prescription records
- ii. Purchase Invoices for all prescription drugs
- iii. Biennial controlled substances inventory
- iv. U.S. Official Order Forms (DEA Form 222)
- v. Power of Attorney for completion of DEA 222 forms
- vi. Theft and Loss Reports (DEA Form 106)
- vii. Record documenting return of drugs to wholesaler or manufacturer
- viii. Record documenting transfers or sales to other pharmacies, licensees and prescribers

Pharmacy records may be stored off-site only if the pharmacy has obtained a waiver from the Board of Pharmacy. There are numerous other provisions applicable in this scenario.

(H) Shipment & Delivery Policy

Dangerous drugs and devices are delivered to the pharmacy, and must be signed by a pharmacist.

(I) BOP Email List

Each pharmacist must maintain subscription to the pharmacy board's e-mail notifications.

(J) Refusing to Fill

A pharmacist must prevent the dispensing of:

- i. A prescription order that is contrary to the law.
- ii. A prescription order the pharmacist has determined would cause harm or otherwise adversely affect the patient’s medical condition.
- iii. Any prescription deemed not for legitimate medical need

No prescription that contains significant error, omission, irregularity, uncertainty, ambiguity or alteration shall be dispensed without clarification and confirmation from the prescriber.

Pharmacists should note their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes. (H&SC 11153) Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b]) Any refusal to fill should be documented in the QA Binder, with an explanation, supporting paperwork, and a copy of the original if possible. The pharmacist may be called upon to justify the refusal.

If a pharmacist refuses to fill particular medications due to personal beliefs, that objection must be submitted in writing in advance and kept on file.

(K) Annual Policy Review

The Policies and Procedures Manual shall be reviewed annually and notated on the Annual Review page.

ANNUAL POLICY REVIEW DOCUMENTATION

Date of Review

Reviewed By: (Print, Sign and describe Position)

Findings and Recommendations

ANNUAL POLICY REVIEW DOCUMENTATION

Date of Review

Reviewed By: (Print, Sign and describe Position)

Findings and Recommendations

SECTION 2: CUSTOMER SERVICE

(A) Philosophy

The Shingle Springs Band of Miwok Indians is the primary governing body, and the Pharmacy's intended objective is to provide exceptional health service to the Community. In addition, the Pharmacy must provide the same professional, ethical, and customer-service oriented services to any and all patients presenting.

(B) Acknowledging / Greeting Patients

Patients must be quickly acknowledged or greeted upon arrival to the counter or by phone, even if employees are occupied. The employee shall greet the patient, and convey that they will be helped momentarily. Failure to promptly acknowledge a patient who has been waiting at the counter is unacceptable.

(C) Returns

Prescription medications that have been dispensed and left the pharmacy are forbidden by law to be 'returned' and put back into inventory. In general, 'returns' are not acceptable. If accountable to Pharmacy Error, the transaction may be refunded and the medication put with waste/outdates – the Pharmacist on Duty must approve the acceptance of the return.

(D) Verbal or Physical Abuse or Intimidation

Customer service in a pharmacy can be difficult; there may be occasions when a patient becomes upset or emotional. These occurrences must be handled professionally, and with tact. The employee shall maintain a helpful, professional demeanor while not being subjected to verbal or physical abuse.

In the event of physical or verbal abuse, the employee should notify the Pharmacist on duty and the Pharmacy Director immediately. The Clinic Manager will be notified immediately and if needed Tribal Police should be notified. An Incident Report documenting the interaction, whether in person or via phone, will be made and filed in the QA binder and a copy will be given to the Clinic Manager.

(E) Referring Patients to the Pharmacist

All New Prescriptions require Pharmacist Consultation. The patient may refuse consultation directly to the Pharmacist. Pharmacy personnel are not allowed to 'screen' patients before referring to the Pharmacist for New Rx Consultation, and should not directly accept a patient's refusal.

SECTION 3: Standards of Practice

Standards of Practice are adapted from the IHS Indian Health Manual

[Indian Health Manual, Part 3, Chapter 7](#)

https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p3c7_ap_a

(A) Assure Appropriateness of Therapy

The pharmacy shall assure that drug therapy is safe, efficacious, and cost effective. A pharmacist shall review the medical record of each patient prior to the dispensing medications. Concerns or questions about the drug therapy shall be resolved with the prescriber prior to dispensing. Pharmacists shall screen patient health records and monitor patients for the appropriateness of therapy with attention to the following

- i. correct patient
- ii. legality of drug orders
- iii. completeness of medication orders
- iv. drug-induced or drug-related problems
- v. appropriateness of drug therapy
- vi. interactions: drug-drug, drug-diet, and drug-lab test
- vii. conditions that require order change or modification
- viii. appropriateness of the dose form
- ix. appropriateness of the dose

Pharmacists shall document their patient record reviews and monitoring. Compliance with this standard shall be assessed by a review of patients' conformance to prescribed drug therapy and evidence of documentation of pharmacists' review.

(B) Patient Education

Patients who present to the pharmacy shall receive medication counseling in a secluded consultation area. The pharmacist shall educate patients regarding the purpose, proper use and expected outcomes of the drug therapy, and will determine patient understanding through patient or caretaker feedback. Supplemental written information shall be provided as necessary.

Counseling shall include the following:

The indication for which the patient is taking the medication; the name and strength of the medication; how the medication is to be used; dosage and administration schedule; technique; duration of therapy; preparation for use; medication storage; ancillary instructions; desired therapeutic outcome; potential unwanted effects and minimization; other treatment plan elements.

(C) Assure Availability of Medications

The pharmacy will assure drug availability; distribution and control are safe and appropriate and meet patient need. Drug and dosage form selection, purchasing, preparation and dispensing shall meet contemporary, national standards. Controlled substances shall be distributed and controlled according to current federal law and regulations and the *Indian Health Manual*, Section 3-7.23, pages 34-39 (Appendix 3D) and as amended. The pharmacy service shall maintain an appropriate inventory of drugs. Provision shall be made for determining the need for medications not routinely available at the facility and for obtaining needed medications that are not routinely available. The pharmacy service shall assure that quality medications are available at reasonable cost according to the current market supply.

(D) Cytotoxic Drugs

Cytotoxic drugs shall be handled according to the current practice standards of the American Society of Hospital Pharmacists: ASHP Technical Assistance Bulletin on Handling of Cytotoxic Drugs in Hospitals, and in the current Occupational Safety and Health Administration (OSHA) guidelines. Compliance with this standard shall be assured by comparing current services with the listed standards of other professional organizations and current applicable IHS policy.

(E) Drug Information and Consultation

The pharmacy shall provide drug information and education by a variety of methods, including:

- a. Pharmacist-initiated, patient-specific interventions
- b. Drug therapy consultation on request from other professional staff
- c. In-service education to other professionals and health workers such as community health representatives and health aides.

Other methods of providing drug information and education may include publishing drug therapy bulletins and/or drug information handouts for patients or providers.

The patient has the right to refuse patient counseling; however, they may be specific situations where the pharmacist may not dispense a medication without counseling when it is deemed medically necessary. Patient education and counseling does not only apply to prescription medications but also to Over-the-Counter medications as well. In certain circumstances, it may be necessary to provide this education over the phone.

Compliance with this standard shall be assessed by review of records of interventions and consultations and documentation of in-service education and preceptor activities.

(F) Promote Health and Disease Prevention

Pharmacies shall promote primary disease prevention through preventive drug therapy and drug use education. Such activities may include:

- i. Reviewing the patient's complete medical record as a part of routine screening for documentation of needed health maintenance activities e.g., Pap test, immunizations, dental fluoridation, and assuring the initiation of needed health maintenance activities
- ii. Discussing safe and appropriate drug use and storage as an integral part of all patient education and consultation activities
- iii. Routinely counseling prenatal patients on safe drug use during pregnancy
- iv. Participating in community-based drug education, poison prevention and substance abuse avoidance programs and activities. Examples of settings in which pharmacists might provide these programs and activities are schools, elderly care centers and health fairs.

To prevent complications from previously diagnosed disease, pharmacists shall provide secondary disease prevention services through routine screening for appropriate drug therapy and providing patient consultation on prescribed therapy.

Compliance with this standard shall be assessed by review of documentation in patients' medical records and documentation of follow-up on needed health promotion and disease prevention measure's.

SECTION 4: Pharmacy Personnel

(A) Job Descriptions

i. Pharmacist

Pharmacist duties are often dynamic, and rely on professional judgement. Some basic duties include, but in no way limited to:

Patient consultation;	Answering telephones;
Prescriber consultation;	Furnish emergency
Reading and interpreting	contraception;
written Rx's;	Interprets clinical data in EMR;
Transcribing Rx's from	Performs any other duty which
telephone or voicemail;	federal or state law or
Typing, Filling and dispensing	regulation authorizes only a
Rx's;	registered pharmacist to
Receiving drug orders;	perform;
Submitting drug orders;	Performs all functions which
Supervision of Techs and Staff;	require <i>professional judgment</i> .

By law, CA pharmacists must be registered for access to the CURES Prescription Drug Monitoring Program.

ii. Intern Pharmacist

The intern pharmacist may perform all the functions of a pharmacist, but *only* under the direct supervision of a pharmacist. A pharmacist may supervise two interns at any one time.

All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist.

During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist.

iii. Technician

All pharmacy technicians must maintain active licensing. Registered pharmacy technicians will perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of the pharmacist on duty. Along with clerks, pharmacy technicians will assume primary responsibility for phone calls and customer service at the windows.

Technicians will not count or handle open bottles of controlled drugs or narcotics until their technique has been observed and approved by the managing pharmacist.

Each pharmacy technician or trainee wears identification that identifies them as a technician or technician trainee. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours.

iv. Clerk

A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into the computer system, and at the direction of a pharmacist *may request and receive refill authorization*. The number of non-licensed personnel supervised by each pharmacist does not interfere with the pharmacist's responsibilities or performance.

v. Director of Pharmacy

Professionally competent, legally qualified pharmacist. The director of pharmacy should be thoroughly knowledgeable about pharmacy practice and management. According to IHS policies, the Director shall foster the Profession of Pharmacy, participate in professional organizations and take initiative to enhance their own professional standing and that of qualified Staff Pharmacists.

The director of pharmacy shall be responsible for:

- a. Establishing and Maintaining the mission, vision, goals, and scope of services of the pharmacy department based on the needs of the patients served, the needs of the clinic (and any health system of which the clinic may be a component), and developments and trends in health care and hospital pharmacy practice.

- b. Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services of the pharmacy.
- c. Actively working with or as a part of Clinic or health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for the patients served by the institution.
- d. Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services.
- e. Ensuring that patient care services provided by pharmacists and other pharmacy personnel are delivered in adherence to applicable state and federal laws and regulations, hospital privileging requirements, and national practice standards.
- f. 340B Program management oversight and compliance
- g. The pharmacy director will keep current on pharmacy topics by having active membership to relevant professional organizations.
These may include, but are not limited to:
 - National Community Pharmacists Association (NCPA)
 - California Pharmacists Association (CPhA)
 - American Pharmacy Association (APhA)

SECTION 5: Pharmacy Operations

(A) Professional Environment

A professional inter-personal work environment must be strictly maintained. There is zero tolerance for workplace gossip. All interpersonal concerns or conflicts should be directly addressed or brought to the attention of the Pharmacy Director.

All forms of harassment or intimidation are strictly forbidden. Language and demeanor shall remain appropriate and professional at all times.

(B) PDMP

The PDMPs are considered to be a tool for prescribers and pharmacists to monitor and deter prescription medication misuse, abuse, addiction and diversion and ensure appropriate clinical care. PDMP Files uploaded to the State of California FTP site no less often than once weekly. This may be done manually, or by 3rd party contract.

- i. The pharmacist shall access PDMP data during the following activities and discuss any potential abuse or diversion with prescribers:
 - a. Prior to processing an outside prescription for a controlled substance.
 - b. Every 3 months, at a minimum, prior to reissuing or refilling for a chronic controlled substance prescription for Schedules CII-CV medications.
- ii. Pharmacists may:
 - a. Assist with conducting PDMP queries upon prescriber request.
 - b. Assist with provider education regarding report interpretation as appropriate.

(C) Pseudoephedrine

Pharmacy personnel must fulfill the “Self-Certification” requirement of CMEA and place in employee file. Electronic POS registration of each pseudoephedrine OTC purchase is documented for each

transaction. All OTC pseudoephedrine products are stored behind the pharmacy counter, and purchasers must present valid official state or federal ID and must be eighteen years old.

(D) Emergency Birth Control

The purpose of this policy is to ensure that emergency contraception is available. This includes Plan B One-Step®, (Levonorgestrel) emergency contraception (EC) pill.

June 2013, the Food and Drug Administration (FDA) approved Plan B One-Step® (Levonogestrel) for over-the-counter (OTC) availability for females of all ages without a prescription (Rx). According to the American College of Obstetricians and Gynecologists, there are no medical contraindications to the use of an EC. The distribution of the Plan B One-Step® EC pill, does not require any of the following: a prescription, a pregnancy test, age verification, patient registration, a provider visit or Electronic Health Record (EHR) documentation. EC will be available to all females including female victims of sexual assault and to their patient representatives in accordance with the June 2013, FDA determination.

(E) Hypodermic Needle and Syringe Sales

The sale of hypodermic needles or syringes without a prescription to any person not meeting either criteria is against pharmacy policy.

(F) Naltrexone

THE SSHWCPh will comply with California State Naltrexone Policy.

(G) Drug Stock Maintenance

The pharmacy shall maintain that drug stock is clean, orderly, properly stored, properly labeled and in date. As with the entire pharmacy, drug inventory should remain dust-free and appropriately organized.

Refrigerator

As per requirements, refrigerators and freezers for medication storage must have minimum twice daily temperature logs. Current plans include the use of automated, wireless systems to continually document temperatures and notify personnel with alarms, text, or email.

(H) Reconstituted Medications

Any medicinal product for oral use manufactured in the powdered state which is reconstituted by SSHWCPh personnel shall receive an expiration date consistent with the recommendations of the manufacturer. Any such medication shall be labeled with the expiration date and stored under the conditions recommended by the manufacturer.

Powdered drugs are not mixed until the patient has arrived to pick the order up.

- All technicians and clerks must be able to identify reconstitutable drugs, and prevent dispensing unmixed product.

(I) Multi-Dose Vials

Medication dispensed from a multiple dose vial (MDV) is withdrawn according to USP 797 standards or those of the manufacturer and a label denoting the date of first entry of the vial is placed on the

vial. The vial is stored appropriately, e.g. room temperature or refrigerated. The vial is discarded 28 days after the initial entry, or according to the manufacturer's recommendation and USP 797.

(J) Special Orders: OTC

At the discretion of the pharmacy staff with considerations such as cost, availability of return, history of past orders, etc. a non-stocked item may be ordered for a specific patient request. Upon receiving the item, the pharmacy will call the customer who requested it. The items will be kept for 14 days. If they have not been purchased, they may be sent back to the wholesaler for credit and return.

The pharmacy will not order special order items from sources other than the primary wholesaler

(K) Special Orders: Rx Items

In general, requests for specific generic brands due to patient preference cannot be accommodated. The wide variation in wholesale cost and low reimbursement rates prohibit the purchase of specific generic manufacturers; often times 2-3 times the cost of a preferred generic. The pharmacist may make exceptions under certain circumstances but is encouraged to find alternative measures.

(L) Drug Samples

Drug samples are not allowed to be intermixed with in-date pharmacy inventory. Samples should be stored in a separate, locked cabinet/closet within the Health Center. Receiving, distribution, and appropriate documentation are performed by the prescriber or the prescriber's agent according to policy. Unwanted or expired drug samples may be placed in the pharmacy 'Outdates and Recalls' container for destruction.

(M) Recalled Medications

Notification of drug recall may be made through several sources, including but not limited to, local and national media, wholesaler, FDA website, manufacturer, or the CA BOP email list. For any level of product recall or withdrawal by the FDA, the Pharmacy will act immediately: stock is examined in the Pharmacy and Health Center for recalled products or lot numbers. If a recalled product is found, it is removed from stock and returned to the appropriate agency per the recall letter instructions. If found, copies of recall documentation are initialed, dated and filed for at least two years. If the product is recalled at the consumer level, every effort will be made to track down and notify patients who may be affected of the recall.

(N) Expired Drugs

Expired drugs or supplies are all returned to the pharmacy for disposition by the pharmacy. This may include return to the manufacturer or wholesaler or for credit or destruction by a return processing company on a regular basis.

(O) Outdated and Recalled Inventory

A segregated container shall be used to isolate drugs that must not be in the dispensing inventory. CII medications shall be counted and marked on the bottle, and kept in a similar, locked container.

SECTION 6: Prescription Dispensing Procedure

(A) Scope

The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, or to another pharmacy of common ownership.

(B) Receipt of Prescription from Patient

Patient information should be documented on the hard copy, including spelling of name, DOB, phone, address, and allergy details. This information should be kept up to date and re-verified with the patient on a regular basis.

(C) Rx Transfers

Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])
Schedule III, IV and V prescriptions can be transferred only once. (CFR 1306.25, CCR 1717[f])
When receiving a transfer, the prescription is reduced to writing by the pharmacist and “transfer” is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

(D) Verbal Prescription Orders

Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. If orally transmitted, the pharmacist who received the prescription initials and dates the prescription.

Facsimile prescriptions are received only from a prescriber’s office, and must contain a ‘wet signature’ for controlled (CIII-CIV) drugs, as required by law.

(E) Rx Day Supply

The pharmacy may dispense a maximum of 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs). If the prescription specifies an initial quantity of less than a 90-day supply, followed by periodic refills, a 90-day supply may be dispensed if: i) The patient has completed an initial 30-day supply; ii) The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills.

(F) Filling of Prescription

Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser.

(G) Prescription Labels

13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])

13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.

13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a] [2])

13.4.3 When applicable, standardized directions for use are utilized.

If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface.

13.4.4 The federal warning label prohibiting transfer of controlled substances is on the prescription container.

13.4.5 The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules.

On controlled substances (13.18), the pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container.

(G) Controlled Substances

All State and Federal Regulations are to be strictly followed. Several statutes follow, however this is in no way a comprehensive list of requirements.

Schedule II prescriptions, invoices, US official order forms, and inventory records are separate from Schedule III, IV and V and indicates on the inventory record whether that inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])

Schedule III-V prescriptions are maintained by the pharmacy software system - easily identifying controlled substances by prescription number, and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

Official Order Form (DEA Form 222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the form, which is then signed by the pharmacist and retained for 5 years.

When dispensed upon a verbal order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

Pharmacist will hand initial prescription records or prescription labels, or record their identity as the reviewing pharmacist in a secure computer system.

All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

A faxed prescription for a Schedule II controlled substance is not fillable.

If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

Electronic image transmissions and faxed prescriptions are printed as a hard copy and filed.

A computer generated prescription that is not an e-script, and is printed out or faxed by the practitioner's office must be manually signed by the prescriber. (Applies to CIII-CV Only)

Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed upon receiving a signed, detailed order from Hospice.

(H) Final Verification of Prescription

Before dispensing, a prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label, or logs similar data in the pharmacy software. (B&PC 4115, CCR 1793.7, CCR 1712)

(I) Patient Counseling

Pharmacists provide oral consultation whenever the prescription drug has not been previously dispensed to the patient; whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new directions; upon request; and whenever the pharmacist deems it is warranted.

Consultations shall be in a manner that protects the patient's information, in an area suitable for confidential patient consultation. The pharmacist will review a patient's drug therapy and medication record prior to or during consultation. Appropriate drug warnings must be provided orally or in writing.

If prescription medication is *mailed or delivered*, written notice about the availability of consultation is provided.

The pharmacist shall provide patient-specific drug information about drugs and drug therapy to health professionals, patients, and patients' caregivers as appropriate. Responses to general and patient-specific drug information requests shall be provided in an accurate and timely manner by a pharmacist.

Pharmacists shall be available to participate in patient education and to ensure that all patients are given adequate information about the medications they receive in to help patients with their own health care decisions. Patient education activities shall be coordinated with the nursing, medical, and other clinical staff as determined by Administration.

If necessary, interpretative language services (written or oral) will be made available to patients.

(J) Language Barriers

To the best of their ability, pharmacy staff will assist patients with limited or no English proficiency to understand the information on the prescription label, or supplemental paperwork in the patient's language. In such a situation the pharmacy may use documentation in the patient's language, or employ the use of an interpreter. SSHWC utilizes Cyracom when in need of a medical interpreter. See attached instruction sheet at the end of these policies. Patient comprehension is the responsibility of the pharmacy, regardless of patient language.

(K) Refills

Authorization is obtained from the prescriber and documented before refilling a prescription.

Refills for Schedule II controlled substances are prohibited, and refills for Schedule III and IV prescriptions are limited to a maximum of 5 fills within 6 months, and all refills taken together do not exceed a 120 day supply.

Pharmacy Technicians and Clerks may both request and receive refill authorizations by phone for *Non-Controlled Medications Only*.

Written documentation of refill authorizations must include the Date, Name of Patient, Name of Prescriber, name of staff person calling, drug name, strength, quantity and additional number of refills. The person recording such authorization must clearly indicate their identity on the new hard copy.

(L) Early Refills

Early refills for high-risk medications will not be acceptable without a legitimate reason and prescriber approval. If the patient is under our Controlled Substance Agreement, the patient must obtain prescriber approval for early fills ahead of time.

(M) Medication Loan Policy

Prescriptions may be filled without the prescriber's authorization if the prescriber is unavailable if, in the pharmacist's professional judgment, failure to refill the prescription may interrupt the patient's ongoing care or have significant adverse effect on the patient. The quantity dispensed should be the minimum sufficient until the anticipated return of the prescriber. Controlled medications are up to the judgment of the Pharmacist on duty.

(N) Schedule II Emergency Dispensing

In the event of lost/stolen medication SSHWC-Ph does not accept Police Reports. Prescriptions will not be refilled without the provider writing a new prescription for the lost or stolen medications.

In absolute *emergency*, the Pharmacist on duty *may* dispense the smallest quantity of C2 medication needed to tide a patient until the following day; however, this may only be done after an exhaustive attempt to contact the prescriber, and may not occur any time prior to the next 'appropriate fill date'. CURES must be checked and documented.

Note: Emergency is defined as; impending loss of life; causing acute injury or illness that poses immediate risk to a person's life or long-term health.

Note: Nearly any 'Emergency' scenario presenting inside the pharmacy can be referred to a nearby Emergency Room, Urgent Care or 911 Services if Clinic Providers are inaccessible.

(O) Errors and Discipline

Whenever the pharmacist or Pharmacy Director sees an error being made by a technician or pharmacist, an informal discussion memo will be generated and discussed with the employee. This should be done as soon as possible after the error is discovered, but no later than 7 days. If more immediate action is necessary, the pharmacist or Pharmacy Director will fill out a corrective action plan (supplied by the Human Resources Department) and begin the SSHWC disciplinary process as stated in the Human Resource Manual.

SECTION 7: NSSC PRICING PROGRAM

National Supply Service Center, NSSC, is a discounted Drug Pricing program that allows eligible facilities to purchase medications at VA Pharmacy Prime Vendor prices. Participation in this program requires strict adherence to the program guidelines. In general, the use of and proceeds from NSSC Medications is intended for Native Americans and Tribal Members. With appropriate Tribal Resolutions, the scope of eligible persons may be broadened, but careful documentation is required to demonstrate compliance with program requirements.

Program compliance consists of 2 main categories: 1. Patient/Rx Eligibility, 2. Non-Profit use of NSSC proceeds.

Patient and Rx Eligibility

1. Tribal Members and Native Americans are eligible to receive NSSC sourced medications for any prescription filled at the SSHWC Pharmacy, regardless of origin.
2. The spouses and dependents of Tribal Members under the age of 18 are also eligible
3. By Tribal Resolution, the Tribe has elected to make *established patients* of SSHWC eligible for NSSC sourced medications. Patient and prescription eligibility must be determined and recorded at the time of dispensation.
 - a. Eligible patients receive Primary Care at the Clinic
 - b. The Clinic must be 'responsible for the patients health care'
 - c. Dental, psychiatric and 'drop-in/urgent' appointments do not, on their own, establish patient eligibility in the absence of routine care
4. Eligible Prescriptions must originate within the Clinic, by Clinic Prescribers. Prescriptions written by a Clinic Provider but originating from a non-SSHWC location are not eligible, nor are orders from outside providers. This does not apply to Tribal Members.
5. NSSC Inventory is separate from commercial inventory both physically and electronically, and maintains auditable records.

NSSC Proceeds and Use

1. Net Profit from NSSC participation (NSSC Proceeds) must be reinvested to add, enhance or expand patient services, or to continue those services funded by the program
2. NSSC Proceeds and use shall be documented in auditable format to ensure program integrity.
3. Examples of eligible services, but not limited to:
 - a. Discounted/no-cost medication/vaccine services to uninsured or underinsured patients
 - b. No-Cost Rx delivery or mail service to Tribal Members, seniors, or disabled patients
 - c. No-Cost compliance packaging (blister packs, etc) for high risk individuals
 - d. Targeted high-risk disease or patient demographic program
 - i. Suicide Prevention
 - ii. Hepatitis Treatment
 - iii. Vaccine Preventable Diseases
 - e. Clinical Pharmacy Programs
 - i. Anticoagulation, Lipids, CHF, Diabetes, etc.

SECTION 8: STAFF TRAINING

(A) Performance Reviews

There shall be regularly scheduled evaluation of the performance of pharmacy personnel. The evaluation format should be consistent with that used by the Clinic. The competencies of the position shall be well defined in the position description, short- and long-term goals should be established for each employee, and the employee's competency shall be assessed regularly. The pharmacy director shall ensure that an ongoing competency assessment program is in place for all staff, and each staff member should have a continuous professional development plan.

(B) Education & Training

All personnel shall possess the education and training required to fulfill their responsibilities and shall participate in relevant continuing-education programs and activities to maintain or enhance their competence. Licensed employees must remain current, up-to-date licensure.

(C) Documentation of Competencies

Employee training and compliance documentation will be maintained in an individual binder within the pharmacy. Employee performance reviews will be maintained separately by administration.

(D) HIPAA Training

HIPAA training will be renewed annually, and the completed forms held in the employees training binder.

Patient information must be maintained to safeguard confidentiality, and all HIPAA regulations must be strictly followed. All prescriptions are kept confidential and only disclosed as authorized by law. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. Staff must maintain private pass codes, and lock unattended terminals within reach or sight of the general public.

Remember: Patient identifiable items must be disposed in a HIPAA compliant manner.

(E) Medicare FWA

Pharmacy staff must certify and record annual Medicare Fraud, Waste and Abuse training.

Key FWA points are:

Participating pharmacies will comply with all applicable laws, rules, and regulations, including, without limitation, the Social Security Act, Medicare Part D implementing regulations, 42 CFR Parts 400-423, CMS instructions and the federal anti-kickback statute, 42 USC §1320a-7b(b), as any of which may be amended from time to time.

The participating pharmacy represents that neither it nor any of its owners, directors, officers, employees, or contractors are subject to sanction under the Medicare/Medicaid program or debarment, suspension, or exclusion under any other federal or state agency or program, or otherwise are prohibited from providing services to Medicare or Medicaid beneficiaries.

(F) Medicare Part D

As required under 42 CFR 423.505(l)(2), for a period of *ten (10) years* following the final year of the Term in which Pharmacy provides Services under any Medicare Part D Program, Pharmacy will maintain, preserve and make available for inspection and review all books, contracts, documents, papers, and other records of Pharmacy, its related entities, contractors, subcontractors, or transferees, that pertain to Medicare Enrollees, the services provided under this Agreement or other matters relevant to Part D Plans (collectively, the "Records"), in accordance with security and privacy protections described.

Notwithstanding the foregoing, the ten-year retention period may be extended if:

- i. CMS determines there is a special need to retain a particular Record or a group of Records for a longer period and notifies the Pharmacy at least 15 days before the normal disposition date
- ii. There is a termination, dispute, or allegation of fraud or similar fault by any Part D Plan Sponsor, in which case the retention may be extended to six (6) years from the date of any resulting final resolution of the termination, dispute or fraud or similar fault;
- iii. Records that relate to an ongoing investigation, litigation, or negotiation by CMS, DHS, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or the Records otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(G) Licensure

All licensed personnel must maintain active licensing in good standing with their respective boards. In the event of license expiration or other sanctions, the licensee must notify the Pharmacy Director and Clinic Manager immediately and discontinue all activities subject to said license.

SECTION 9: Conduct

(A) Personal Use of Telephones

General use is not allowed on the Pharmacy Floor, limited to break areas (except for pharmacy-specific reference applications). Distractions are not allowed while working.

(B) Internet and E-Mail Use

Employees may access their work email system when appropriate, but must refrain from 'Social Computer Use'. Computer use should never take priority over patients and telephones.

(C) Breaks and Lunches

Employees must take breaks and lunches as scheduled. Lunch time will be 12:00 – 1:00 daily, during Pharmacy and Clinic closure.

(D) Eating and Drinking in Pharmacy

Food and Drink are not allowed at work stations or terminals.

(E) Smoking

Smoking must be limited to designated areas, not within sight of patients entering/exiting the clinic.

(F) Visitors

Employees may socialize with visitors on breaks and lunches. Patients should never be neglected over social or non-pharmacy conversation.

SECTION 10: Dress Code

(A) Name Badges

All staff must wear identification, displayed above the waist and visible from across counters.

(B) Clothing

Clothing must be work appropriate, shorts and open toe shoes are not allowed in the pharmacy. Staff will wear the assigned Polo shirts and colored smocks provided by SSHWC with professional pants or skirts. No jeans. Staff will be given five (5) shirts at the start of their employment. Shirts can and will be replaced every two years or when the need arises such as when they become ripped, torn or stained.

SECTION 11: TIME AND ATTENDANCE

(A) Scheduling

Schedules will be available 2 weeks ahead of time, and must be acknowledged by employee. Any scheduling conflicts must be addressed as far in advance as possible.

(B) Sickness / Informing Management

If unable to attend work, the employee must notify the Pharmacy Director two hours in advance of shift and in accordance with Human Resource policies.

SECTION 12: SAFETY

(A) Maintaining a safe work environment in accordance with SSHWC policies.

b. Poison Control Center

Poison Control is a primary resource for poisoning information and helps reduce costly emergency department visits through in-home treatment. Poison centers offer free, confidential medical advice 24 hours a day, seven days a week through the Poison Help Line.

Poison Help Line 1-800-222-1222

Because of the urgency and special area of expertise, any inquiries regarding exposure anything outside normal use, will be quickly referred to the poison control hotline.

Any staff may refer any person to the poison help line.

This call is encouraged to be made by the person reporting the incident so they can best receive the information as well as provide information to the service. If this cannot be done, a staff member may call on their behalf. A phone call to 911 or Tribal Police should be considered in an emergency situation.

SECTION 13: SECURITY

(A) Access by Non-Pharmacy Personnel

Only registered pharmacists may possess keys to the actual pharmacy. Non-Pharmacy personnel may only enter the pharmacy with consent of the Pharmacist on duty.

(B) Security Precautions

- i. Management and staff should not discuss pharmacy procedures, cash handling, pharmacy layouts, security systems, etc., with *any* outsider, even family.
- ii. Pharmacy personnel should not discuss inventory controls with other employees.
- iii. Co-workers or other pharmacy personnel do not need to know the measures taken to hide targeted drugs.
- iv. Staff should be alert and observant. They should quickly acknowledge and regularly offer assistance to clients

(C) Robberies

In the face of crisis, stay calm and comply with the demands of the intruder.

Advice from the DEA:

What to do during a robbery:

- Do not resist; cooperate fully with the robber.
- Remain calm and avoid sudden movements.
- Do exactly what you are told to do, nothing more and nothing less.
- Make mental notes on a physical description (e.g., clothing, hair, size, build, tattoos, scars, and other body features).

- Do not attempt to apprehend the criminal yourself.

What to do After a Robbery:

- Immediately get treatment for anyone who may be injured.
- Sound the alarm as soon as possible.
- Call Tribal police first, then your supervisor who will then notify the Clinic Manager.
- Lock doors immediately to prevent re-entry and keep closed until police arrive.
- Request customers to remain in the store to give a statement to police.
- Protect the crime scene. Stop others from touching anything touched by the suspect(s).
- Do not trust your memory. The quicker you write down what you observed the better.

(D) Burglaries

What to do after a burglary:

- Notify Tribal police department.
- Avoid touching or disturbing anything.
- After the police arrive, prepare a detailed list of what was stolen.
- Take the appropriate steps to improve security.

(E) Reporting Theft or Loss of Controlled Medications

If controlled drugs were taken, report it to your local DEA Field Office in writing within one business day, and submit a completed DEA Form 106, Report of Theft or Loss of Controlled Substances, as soon as possible.

A report should also be filed with the State Board of Pharmacy.

APPENDIX

Incident Report: Quality Assurance Binder

[Incident Report_SSCHWCPH.pdf](#)

Board of Pharmacy: Self Assessment

[Community Pharmacy Self-Assessment](#)
www.pharmacy.ca.gov/forms/17m_13.pdf

Indian Health Manual: Part 3, Ch7

[Indian Health Manual, Part 3, Chapter 7](#)
https://www.ihs.gov/ihtm/index.cfm?module=dsp_ihm_pc_p3c7_ap_a

DAW

DAW(dispensed as written) – Standard NCPDP Codes are:

- 0 = No product selection indicated
- 1 = Substitution not allowed by prescriber
- 2 = Substitution allowed - patient requested product dispensed
- 3 = Substitution allowed - pharmacist selected product dispensed
- 4 = Substitution allowed - generic drug not in stock
- 5 = Substitution allowed - brand drug dispensed as a generic
- 6 = Override
- 7 = Substitution not allowed - brand drug mandated by law
- 8 = Substitution allowed - generic drug not available in marketplace
- 9 = Other

REFERENCES

Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see Laws and Regulations), at the California State Law Library, or at other libraries or Internet web sites.
California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)



SHINGLE SPRINGS BAND OF MIWOK INDIANS

Shingle Springs Rancheria, (Verona) Tract, California
5281 Honpie Road, Placerville CA 95667
P.O. Box 1340, Shingle Springs CA 95682
(530) 676-8010 Office; (530) 676-8033 Fax

RESOLUTION 2017-36

SUBJECT: APPROVAL OF PHARMACY POLICIES AND PROCEDURES MANUAL.

WHEREAS, the Shingle Springs Band of Miwok Indians (the "Tribe") is a federally recognized Indian tribe eligible for the special programs and services provided by the United States to Indians because of their status as Indians and is recognized as possessing powers of self-government; and

WHEREAS, the Shingle Springs Tribal Council is the duly-elected governing body of the Tribe and is authorized to act on behalf of the Tribe; and

WHEREAS, the Tribe operates the Shingle Springs Tribal Health Program ("SSTHP"), located on the Shingle Springs Rancheria; and

WHEREAS, the SSTHP has established a pharmacy in the Shingle Springs Health and Wellness Center; and

WHEREAS, the Tribal Council finds it necessary to adopt policies and procedures for the management and operation of the pharmacy; and

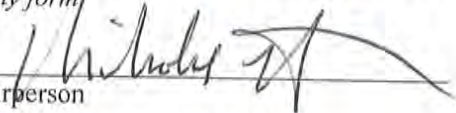
WHEREAS, the Tribal Council has reviewed the attached Pharmacy Policies and Procedures Manual and has determined that it is consistent with the Tribe's goals for the pharmacy.

NOW THEREFORE, BE IT RESOLVED that the Tribal Council hereby approves the attached "Pharmacy Policies and Procedures Manual" and authorizes the Chairman or his designee to execute any and all documents and agreements necessary as may be required to give effect to the transaction, herein contemplated, and to take such other actions as may hereby be necessary and appropriate to carry out the obligations thereunder.

BE IT FURTHER RESOLVED that this resolution will take effect immediately.

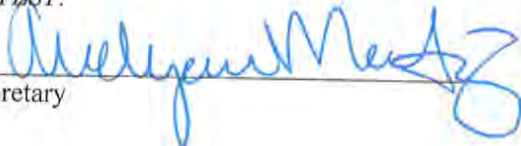
CERTIFICATION

As a duly-elected official of the Shingle Springs Band of Miwok Indians, I do hereby certify that, at a meeting duly called, noticed, and convened on the 1st day of June, 2017 at which time a quorum of 7 was present, this resolution was duly adopted by a vote of 7 FOR, 0 AGAINST, 0 ABSTAINED, and said resolution has not been rescinded or amended in any form


Chairperson

June 1, 2017
Date

ATTEST:


Secretary

June 1, 2017
Date