PROPOSAL: To Adopt Professional Policies Related to Regulatory Issues

SUBMITTED BY: Board of Directors

DATE SUBMITTED: August 19, 2014

SITUATION:

1. CSHP professional policies are developed from recommendations (from the House of Delegates), resolutions (from members) and from the work of committees and task forces.

2. The Board of Directors also reviews ASHP policies & other guidance documents for consideration as CSHP Professional Policy.

3. During this process, CSHP's professional policy catalogue is checked for policies relating to the topic under review.

4. The large number of proposals thus created lends itself to grouping by topic to facilitate consideration by the House of Delegates.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012 - 2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP's professional policies accurately reflect current practice and professional standards.

PROPOSAL:

To adopt as CSHP professional policy:

Proposal G – Proposals Related to Regulatory Issues

- G1 To Adopt ASHP Policy 0909, Regulation of Interstate Pharmacy Practice
- G2 To Adopt ASHP Policy 1003, FDA Authority on Recalls
- G3 To Adopt ASHP Policy 1007, Regulation of Home Medical Equipment Medication Products & Devices
- G4 To Adopt ASHP 1120 By Modifying CSHP 2011-02 Off Label Meds
- G5 To Adopt ASHP Policy 1310, Regulation of Telepharmacy Services
- G6 To Adopt ASHP Policy 1311, Regulation of Centralized Order Fulfillment
- G7 To Adopt ASHP Policy 1314, DEA Scheduling of Hydrocodone Combination Products
- G8 To Adopt ASHP Policy 1315, DEA Scheduling of Controlled Substances

CSHP BOARD ACTIONS: The CSHP Board of Directors has approved these proposals for consideration by the 2014 House of Delegates.

PROPOSAL: **To Adopt ASHP Policy 0909, Regulation of Interstate Pharmacy Practice**

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 909, Regulation of Interstate Pharmacy Practice

   To advocate that state governments, including legislatures and boards of pharmacy, adopt laws and regulations that harmonize the practice of pharmacy across state lines in order to provide a consistent, transparent, safe, and accountable framework for pharmacy practice.

4. The practice of pharmacy has become increasingly patient-centered as well as product-centered. Many pharmacists provide clinical pharmacist services without being involved in the preparation or dispensing of a product. Pharmacists with the best knowledge and ability to advise, prescribe or manage a particular patient's therapy or to provide the best and safest dispensed product may not reside in the state where the patient is located. For example, pharmacists at "Centers of Excellence", such as oncology medical centers, are more likely to be able to assist with the most complicated patients and their need for personalization of the latest therapy regimens or products.

5. Some states have established unnecessary and impractical barriers to the provision of personalized clinical services or products for their residents, or even visitors, by pharmacists who are not practicing in the patient's state and who do not have a personal pharmacist license in the state where the patient is present. The result is that the patient is denied the best available expertise and products.

6. The limitation also causes increased risk and cost from unnecessary duplicate testing in the state where the patient is present, as well as unnecessary use of medical and pharmacy personnel resources.

7. With the current state and continued emergence of new technology for the sharing of diagnostic and therapy information, and product quality and accuracy assurance, state borders are becoming more artificial and reconsideration for such barriers and coordination between states is increasingly needed to avoid the risks, cost and lack or optimal efficacy and safety caused by unnecessary and impractical barriers to the interstate practice of clinical, patient-centered pharmacy.

8. Likewise, current and continued emergence of new technology for the remote verification of accurate preparation and product dispensing allow that function to be done by dedicated and properly trained and equipped personnel regardless of location and state borders. In fact, by centralization, the latest and best technology is more reliable and affordable in insure patient safety.

9. To achieve the highest level of patient safety, therapeutic efficacy and affordability possible, state regulatory bodies need to work closely together to provide a regulatory framework that does not unnecessarily inhibit interstate pharmacy practice. Dialogue between the professional pharmacist associations and the National Association of Boards of Pharmacy and individual state boards can help reduce unnecessary barriers to the practice of pharmacy across state lines by producing model language that can be adopted by individual states.

10. CSHP does NOT have a policy in CSHP Policy Catalog on Interstate Practice.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012-2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has a professional policy on Regulation of Interstate Pharmacy Practice

4. Patients may receive the best and safest services from any pharmacist regardless of the pharmacist's location in a state different from where the patient is present without unnecessary barriers such as the pharmacist having to be licensed in the state where the patient is present.

PROPOSAL:

That CSHP adopt as professional policy:

Interstate Pharmacy Practice Regulation

The California Society of ~~Health System~~ Health-System Pharmacists:

1. Supports the ability of patients to receive high quality, affordable services from any US pharmacist qualified and equipped to provide such services regardless of the state in which the pharmacist is licensed without any unnecessary or impractical limits on the interstate practice of clinical or product-centered pharmacy.

2. Supports the adoption by state governments, including legislatures and boards of pharmacy, of laws and regulations that harmonize the practice of pharmacy across state lines in order to provide patients with high quality, safe, affordable, practical and accountable framework for interstate pharmacy practice.

PROPOSAL: **To Adopt as CSHP Policy ASHP Policy 1003, FDA Authority on Recalls**

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 1003, FDA Authority on Recalls

   To strongly encourage the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs; further,

   To advocate that such notification should (1) come from a single source, (2) clearly identify the recalled product, (3) explain why the product is being recalled, (4) provide a way to report having the recalled product, (5) give instructions on what to do with the recalled product, and (6) be provided concurrently to all entities in the supply chain; further,

   To advocate that the FDA be given the authority to order mandatory recalls of medications; further,

   To urge the FDA to require drug manufacturers and the computer software industry to provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients; further,

   To urge the FDA to encourage post-marketing reporting of adverse events and product quality issues to enhance the recall system.

4. CSHP does not have a policy on FDA Authority on Recalls.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012-2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has a professional policy on FDA Authority on Recalls.

PROPOSAL:

That CSHP adopt as professional policy,

FDA Authority on Recalls

The California Society of ~~Health System~~ Health System Pharmacists:

1. Strongly encourages the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs

2. Endorses that such notification should:
    a. come from a single source,
    b. clearly identify the recalled product,
    c. explain why the product is being recalled,
    d. provide a way to report having the recalled product,
    e. give instructions on what to do with the recalled product, and
    f. be provided concurrently to all entities in the supply chain

3. Urges the FDA to require drug manufacturers and the computer software industry to provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients

4. Urges the FDA to encourage post-marketing reporting of adverse events and product quality issues to enhance the recall system.

PROPOSAL: To Adopt ASHP Policy 1007, Regulation of Home Medical Equipment Medication Products and Devices

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. Review ASHP Policy 1007 Regulation of Home Medical Equipment Medication Products and Devices:

   To advocate for consistent regulatory oversight of all home medical equipment, with the
   goals of continuity of care, patient safety, and appropriate pharmacist involvement whenever equipment is used for medication administration; further,

   To monitor the impact of the Centers for Medicare & Medicaid Services quality standards on the accreditation of suppliers of medication-related durable medical equipment and supplies.

4. CSHP has the following professional policies pertaining to or mentioning medical devices, none of which deal with device regulation:

   Sales Tax Exemption on Prescribed Medications and Medical Equipment (2010-16)

   The California Society of Health-Systems Pharmacists supports the exemption of sales tax on prescribed purchases of medications, medical supplies, equipment and devices.

   Health-System Use of Medications and Administration Devices Supplied Directly to Patients (2013-19)

   To encourage hospitals and health-systems not to permit administration of medications brought to the hospital or clinic by the patient or caregiver when storage conditions or the source cannot be verified; further

To support only care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further

To encourage hospitals and health-systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients) unless it is determined that the risk of not using such a device exceeds the risk of using it; and

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.

Standardization of Intravenous Drug Concentrations (2013-20)

To develop nationally standardized drug concentrations and dosing units for injectable drugs.

To encourage all hospitals and health-systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety enhancing capabilities.

To encourage interprofessional collaboration on the adoption and implementation of standardized drug concentrations and dosing units in hospitals and health systems.

5. Federal and state regulation of home medical equipment (HME) and durable medical equipment (DME) suppliers creates a gap in pharmacist review and input in medication-related aspects of the services these suppliers provide to patients, particularly when a patient is discharged from the hospital to the home.

6. The Centers for Medicare & Medicaid Services (CMS) provides conditions of participation for home health services; states may regulate HME and DME suppliers, home health agencies, and suppliers of medical gases.

7. The Centers for Medicare & Medicaid Services (CMS) established and implemented Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards under the Medicare Modernization Act of 2003 (MMA). Suppliers must comply with the Quality Standards and become accredited to obtain or maintain Medicare billing privileges unless they are exempt from the accreditation requirement. The ASHP policy states this is to be monitored. CSHP is not likely going to do so.

8. The FDA has oversight to ensure the safety and effectiveness of medical devices.

9. The regulatory oversight of medical products was added to the Government Accounting Office's (GAO) High Risk List in 2009 because FDA was facing a variety of difficulties that threatened to compromise its ability to protect the public health. Considerable challenges exist in this arena, such as medical device recalls, complete implementation of the Safe Medical Devices Act of 1990, overseas production of medical devices, timeliness of the review process and tracking medical product applications for children.

See www.gao.gov/highrisk/protecting_public_health/why_did_study#t=1

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012 - 2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has professional policy on the regulation of medical devices.

PROPOSAL:

That CSHP adopt as professional policy,

Regulation of Home Medical Equipment Medication Products and Devices

The California Society of ~~Health System~~ Health-System Pharmacists supports the consistent regulatory oversight of all home medical equipment, with the goals of continuity of care, patient safety, and appropriate pharmacist involvement whenever equipment is used for medication administration.

PROPOSAL: To Approve ASHP Policy 1120, Regulation of Off-Label Promotion and Marketing by Modifying CSHP Professional Policy 2011-02, Off-Label Use of Medication

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 1120, Regulation of Off-Label Promotion And Marketing

   To advocate for authority for the Food and Drug Administration to regulate the promotion and dissemination of information about off-label uses of medications by manufacturers; further,

   To advocate that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses.

4. There is a policy in the CSHP Policy Catalog on this subject:

   Off-Label Use of Medication (2011-02)

   1. CSHP Supports the practice of prescribing medications for off-label uses that are documented in the medical literature in a system that:
      a) Maintains patient access to pharmacist review of all medications.
      b) Protects the pharmacist's right of refusal of an off-label use of a medication.
      c) Preserves the patient-pharmacist-prescriber relationship.
      d) Provides adequate patient counseling and education, particularly to patients taking medications for off-label use.
      e) Recognizes the prescriber's responsibility in assuring the appropriate and safe use of all medications; and
      f) Encourages evidence-based decision making and prescribing.

   2. CSHP opposes efforts to restrict the off-label use of medication when the usage is medically appropriate, evidence-based and in the patient's best interest

5. The CSHP policy does not address the regulation of off-label promotion and marketing. The ASHP background information points out that without oversight by the FDA, manufacturers

have no incentive to sponsor studies on off-label uses. ASHP argues that the FDA needs authority to regulate promotion of off-label uses similar to that passed by Congress in FDAMA.

6. In order to enable evidence-based decision making and prescribing for off-label uses of medications, the FDA should have the authority to regulate such promotions and marketing, permitting it only following the submission of a supplemental new drug application for use.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012 - 2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has professional policy on the off-label use of medications, but needs to address FDA regulation of off-label promotion and marketing.

PROPOSAL:

That CSHP amend professional policy 2011-02,

Off-Label Use of Medication

The California Society of ~~Health System~~ Health-System Pharmacists:

1. ~~CSHP~~ Supports the practice of prescribing medications for off-label uses that are documented in the medical literature in a system that:
   a) Maintains patient access to pharmacist review of all medications.
   b) Protects the pharmacist's right of refusal of an off-label use of a medication.
   c) Preserves the patient-pharmacist-prescriber relationship.
   d) Provides adequate patient counseling and education, particularly to patients taking medications for off-label use.
   e) Recognizes the prescriber's responsibility in assuring the appropriate and safe use of all medications; and
   f) Encourages evidence-based decision making and prescribing.

2. ~~CSHP~~ Opposes efforts to restrict the off-label use of medication when the usage is medically appropriate, evidence-based and in the patient's best interest

3. Recognizes the authority of the Food and Drug Administration to regulate and restrict the promotion and dissemination of information about off-label uses of medications by manufacturers

~~4. Supports that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses.~~

PROPOSAL: To Adopt ASHP Policy 1310, Regulation of Telepharmacy Services

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 1310, Regulation of Telepharmacy Services

   To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,

   To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9) service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures; further,

   To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.
   This policy supersedes ASHP policy 0716.

4. Telepharmacy services can include clinical consultation, drug therapy monitoring, patient counseling, prescription medication prior authorization and refill authorizations, monitoring of formulary compliance, remote order entry or other services provided by pharmacists or pharmacy technicians with the aid of teleconferencing, video conferencing or other electronic methods.

5. Some states restrict the provision of these services to pharmacists licensed within their state (for example Alabama, Colorado, Maryland, Missouri, Oregon).

6. These services are widely provided; uniform regulations and standards are needed.

7. CSHP currently has no professional policy on telepharmacy.

TARGET:

- CSHP provides resources to its members, their patients and the public per the 2012-2015 Strategic Plan.

- CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

- CSHP will create professional policy on telepharmacy.

PROPOSAL:

That CSHP adopt as professional policy,

Regulation of Telepharmacy Services

The California Society of ~~Health System~~ Health-System Pharmacists:

1. Supports the adoption of laws and regulations that standardize telepharmacy practices for patients within California ~~across state lines~~ and facilitate the use of United States-based telepharmacy services.

2. Encourages the California State B~~b~~oard of P~~p~~harmacy and state agencies that regulate pharmacy practice to include the following in regulations for telepharmacy services:
    a. education and training of participating pharmacists;
    b. ~~education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating~~define the role of pharmacy technicians;
    c. communication and information systems requirements;
    d. remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing;
    e. direct patient-care services, including medication therapy management services and patient counseling and education;
    ~~f. licensure (including reciprocity) of participating pharmacies and pharmacists;~~
    f. service arrangements that cross state borders;
    g. service arrangements within the same corporate entity or between different corporate entities;
    h. service arrangements for workload relief in the point-of-care pharmacy during peak periods;
    i. pharmacist access to all applicable patient information; and development and monitoring of patient safety, quality, and outcomes measure

PROPOSAL: To Adopt as CSHP Policy ASHP 1311 Regulation of Centralized Order Fulfillment

SITUATION:

1. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

2. ASHP Policy 1311 Regulation of Centralized Order Fulfillment, says

   "To advocate changes in federal and state laws, regulations, and policies to permit centralized medication order fulfillment within health care facilities under common ownership"

3. CSHP currently does not have a policy on Regulation of Centralized Order Fulfillment

TARGET:

1. CSHP supports changes in regulation that improve the safety and efficiency of medication therapy such as the concentration of medication order fulfillment for all hospitals and health care facilities in a centralized location where expertise, specialized equipment and efficiency can be concentrated. Such examples include unit dose repackaging with bar code identification for bedside barcode verification for administration in "Critical Access" and "rural" hospitals that are NOT necessarily under common ownership. Such hospitals are the least likely to have their own resources, expertise and equipment for such repackaging when the products do not come from the manufacturer marked as needed.

2. CSHP supports such regulation without arbitrary limitations on common ownership or distribution distance in California.

3. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

4. CSHP has professional policy on the Regulation of Centralized Order Fulfillment.

PROPOSAL:

That CSHP adopts as professional policy,

Regulation of Centralized Order Fullfillment

The California Society of ~~Health System~~ Health-System Pharmacist supports changes in federal and State statute and regulation provisions to permit centralized order fulfillment or repackaging for hospitals and ~~health systems~~ health-systems to improve medication use safety and efficiency in California regardless of common ownership or distribution distance.

PROPOSAL: To Adopt ASHP Policy 1314, DEA Scheduling of Hydrocodone Combination Products

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 1314, DEA Scheduling of Hydrocodone Combination Products

   To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

4. As defined by the DEA, Schedule II controlled substances are those that “have a high potential for abuse which may lead to severe psychological or physical dependence.” Schedule III controlled substances are those that “have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.”

5. The FDA's Drug Safety and Risk Management Advisory Committee, the Centers for Disease Control and Prevention (CDC) and other entities have reported on the extent of abuse and patient harm from these and other opioid analgesics. Recent data from the CDC show that every year since 2003 more deaths have occurred from overdoses of opioid pain relievers, including hydrocodone combination products, than from overdoses of cocaine and heroin combined.

6. In addition to this morbidity and mortality data, the ASHP Council on Therapeutics (the Council) reviewed clinical guidelines on pain management, opioid prescribing trends, and research on the relative addictive potentials of opioid products. The Council found no evidence that the lower dose of hydrocodone contained in these combination products, or the addition of acetaminophen, lowered the abuse potential of hydrocodone. The ASHP Board and House supported this assessment.

7. The Council discussed data contained in the FDA pre-meeting report on prescribing trends (e.g., prescriber type, indication, duration of therapy), abuse potential, and patient harms. The Council questioned whether it reflected the true extent of abuse of these therapies

given the high prevalence of pill sharing and diversion of legal prescriptions. The Board and House agreed.

8. They further noted that adverse drug events and other patient harms may be underreported when these products are misused or obtained illegally and that the FDA data provided no insight as to whether these prescriptions were appropriate (i.e., issued according to evidence-based guidelines for appropriate indications and durations of use). Given these variables, the Council stated that the data are difficult to interpret and apply to a rescheduling decision, and the Board and House agreed. Central to the Council's deliberation were criteria used by DEA to determine whether to control or reschedule a drug, which include
    a. the drug's actual or relative potential for abuse;
    b. scientific evidence of its pharmacological effect, if known;
    c. the state of current scientific knowledge regarding the abuse of the drug or other substance;
    d. its history or current pattern of abuse;
    e. the scope, duration, significance of abuse;
    f. what, if any, risk there is to public health;
    g. its psychic or physiological dependence liability; and
    h. whether the substance is a precursor of a substance already controlled under the law.

9. Based on an assessment using these criteria, the Council, Board, and House believed that hydrocodone combination products were similar to other controlled substances found in Schedule II and should therefore be assigned to Schedule II.

10. Of note, the Council stated that these criteria were never intended to take into account potential administrative and other burdens on pharmacists and other clinicians (e.g., stricter recordkeeping and security processes).

11. The Council also addressed concerns that rescheduling hydrocodone combination products may not decrease abuse. While it is difficult to predict the impact rescheduling would have on abuse, a majority of Council members believed that abuse would decrease, stating that the current extent of abuse is supported by easy access to, and excessive supply of, these therapies. The Board and House agreed with this assessment.

12. The Council also considered a recommendation from the FDA to delay a decision on rescheduling until more data are available concerning the impact of alternative strategies, such as prescription drug monitoring programs, risk evaluation and minimization strategies (REMS), prescriber and patient education, and enforcement actions. The Council stated that these strategies can be effective, but noted that these approaches are largely reactive, not proactive. The Council believed that many of these strategies have been in place for years, yet there has been limited scientific evaluation of their effectiveness despite the costs and burdens they impose. In addition, clinician willingness to follow clinical guidelines and other measures to ensure appropriate medication use of all therapies has historically been low.

13. Overall, the Council questioned whether more or better information would be gained by further delaying a decision on rescheduling these therapies. In light of these findings, the Council, Board, and House believed that continued inaction was inappropriate given the public health concern.

14. In considering this policy, the Council, Board, and House weighed the potential public health benefit of rescheduling these therapies against concerns about restricting patients' access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. The Council, Board, and House believed that these were very significant and valid concerns. However, in balancing these concerns, they concluded that increased control of drugs with high abuse potential is in the best interests of patients and public health.

15. In addition, the Council questioned whether the inability to prescribe refills (which would be a primary impact of rescheduling) would have as broad an impact on patient access as initially feared. The Council highlighted data from the FDA pre-meeting report demonstrating that a majority of prescriptions for these products were issued for treatment of acute pain. The FDA's evaluation of the 131 million prescriptions issued in 2011 found that these products were most commonly prescribed for diseases of the musculoskeletal system and connective tissues; diseases of the respiratory system (for hydrocodone combination products that are used as antitussives); and fractures, sprains, contusions, and injuries. The average duration of therapy was 14 days. The Council stated that this information indicates that the burden on patients and providers should be less than feared because prescriptions for acute pain treatment would have no refills (or limited refills).

16. The Council also noted several factors that would address concerns about access and burden, including the ability to predate prescriptions, proposed changes to e-prescribing standards that would permit electronic prescribing for these therapies, and the ability to fax prescriptions in many instances. However, the Council did acknowledge that existing state practice acts could prevent some mid-level practitioners from prescribing these drugs should a schedule change be implemented. The Council, Board, and House encouraged DEA and others to monitor the impact of this scheduling change on patient access and practice, as well as to monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

17. As part of their discussion, the Council also expressed concern about the current process used by the DEA to determine abuse potential for all controlled substances. A separate policy recommendation was developed to address this topic.

18. The CSHP Policy Catalog has no professional policy on this subject.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012-2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has professional policy on DEA Scheduling of Hydrocodone Combination Products.

PROPOSAL:

That CSHP adopt as professional policy,

DEA Scheduling of Hydrocodone Combination Products

The California Society of ~~Health System~~ Health-System Pharmacists supports the rescheduling of hydrocodone combination products by the ~~Drug Enforcement Administration (DEA) to~~ Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

PROPOSAL: To Adopt ASHP Policy 1315, DEA Scheduling of Controlled Substances

SITUATION:

1. CSHP Professional Policy #2010-04 directs CSHP to adopt ASHP policies & other guidance documents as CSHP Professional Policy:

   To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.

   To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.

2. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.

3. ASHP Policy 1315, DEA Scheduling of Controlled Substances

   To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

   To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current evidence concerning the abuse potential of these therapies; further,

   To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of health care providers.

4. The current stratification of abuse potential into low, moderate, and high categories lacks clarity and contributes to perception of inconsistency in assigning schedules.

5. The existing schedules do not appear to take into account evolving evidence about the abuse potential of these drugs.

6. The scheduling of medications can affect patient access to them; CSHP supports patient access to appropriate drug therapy.

7. There currently is nothing in the CSHP Policy Catalog on this subject.

TARGET:

1. CSHP provides resources to its members, their patients and the public per the 2012-2015 Strategic Plan.

2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society.

3. CSHP has professional policy on the DEA scheduling of controlled substances.

PROPOSAL:

That CSHP adopt as professional policy,

DEA Scheduling of Controlled Substances

The California Society of ~~Health System~~ Health-System Pharmacists:

1. Encourages the Drug Enforcement Administration (DEA) to establish clear, measurable criteria and a transparent process for scheduling determinations.

2. Urges the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current evidence concerning the abuse potential of these therapies.

3. Supports that the DEA monitor the effect of scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of health care providers.