PHYSICIAN ASSISTANT BOARD
NOTICE OF TELECONFERENCE
PUBLIC BOARD MEETING
July 13, 2015
2:30 P.M. – 4:30 P.M.

One or more Board Members will participate in this meeting at the teleconference sites listed below. Each teleconference location is accessible to the public and the public will be given an opportunity to address the Board at each teleconference location. The public teleconference sites for this meeting are as follows:

Charles Alexander, Ph.D.
1232 Campbell Hall
Los Angeles, CA 90095
916-561-8780

Sonya Earley
2020 Zonal Ave, IRD Bldg, Rm 628
Los Angeles, CA 90638
916-561-8780

Catherine Hazeltom
1 Bush St, #800
San Francisco, CA 94104
916-561-8780

Xavier Martinez
4995 Murphy Canyon Rd, #207
San Diego, CA 92123
858-637-7120

Robert Sachs, PA-C
1520 San Pablo St, #4300
Los Angeles, CA 90033
916-561-8780

AGENDA

1. OPEN SESSION - Roll Call & Establishment of a Quorum
   Charles Alexander, Ph.D.
   Michael Bishop, M.D.
   Sonya Earley, PA
   Jed Grant, PA-C
   Catherine Hazeltom
   Xavier Martinez
   Robert Sachs, PA-C

2. Public Comment on items not on the Agenda

(Note: The Board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda for a future meeting. [Government Code Sections 11125, 11125.7(a).])
3. Legislation of Interest to the Physician Assistant Board
   SB 337 Pavley (Physician Assistants)

4. CLOSED SESSION
   Pursuant to Section 11126(c)(3) of the Government Code, the Board will move into closed session to deliberate on disciplinary matters.

5. OPEN SESSION

6. Adjournment

Note: Agenda discussion and report items are subject to action being taken on them during the meeting by the Board at its discretion. All times when stated are approximate and subject to change without prior notice at the discretion of the Board unless listed as “time certain”. Agenda items may be taken out of order and total time allocated for public comment on particular issues may be limited. The meeting may be cancelled without notice. For verification of the meeting, call (916) 561-8780 or access the Board’s Web Site at www.pac.ca.gov.

Notice: The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Anita Winslow at (916) 561-8782 or email anita.winslow@mbc.ca.gov or send a written request to the Physician Assistant Board, 2005 Evergreen Street, Suite 1100, Sacramento, California 95815. Providing your request at least five (5) business days before the meeting will help to ensure availability of the request.
Agenda

Item 3
An act to amend Sections 3501, 3502, and 3502.1 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL’S DIGEST

SB 337, as amended, Pavley. Physician assistants.

Existing law, the Physician Assistant Practice Act, provides for regulation of physician assistants and authorizes a physician assistant to perform medical services as set forth by regulations when those services are rendered under the supervision of a licensed physician and surgeon, as specified. The act requires the supervising physician and surgeon to review, countersign, and date a sample consisting of, at a minimum, 5% of the medical records of patients treated by the physician assistant functioning under adopted protocols within 30 days of the date of treatment by the physician assistant. The act requires the supervising physician and surgeon to select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgment, the most significant risk to the patient. A violation of those supervision requirements is a misdemeanor.

This bill would require that the medical record for each episode of care for a patient identify the physician and surgeon who is responsible for the supervision of the physician assistant. The bill would require a physician assistant who transmits an oral order to identify the name of the supervising physician and surgeon responsible for the patient. The bill would delete those medical record review provisions, and, instead,
require the supervising physician and surgeon to use one or more of
described review mechanisms. By adding these new requirements, the
violation of which would be a crime, this bill would impose a
state-mandated local program by changing the definition of a crime.

The act authorizes a physician assistant, while under prescribed
supervision of a physician and surgeon, to administer or provide
medication to a patient, or transmit orally, or in writing on a patient’s
record or in a drug order, an order to a person who may lawfully furnish
the medication or medical device. The act prohibits a physician assistant
from administering, providing, or issuing a drug order to a patient for
Schedule II through Schedule V controlled substances without advance
approval by a supervising physician and surgeon for that particular
patient unless the physician assistant has completed an education course
that covers controlled substances and that meets approved standards.
The act requires that the medical record of any patient cared for by a
physician assistant for whom a physician assistant’s Schedule II drug
order has been issued or carried out to be reviewed, countersigned, and
dated by a supervising physician and surgeon within 7 days.

This bill would delete that review and countersignature requirement
for a physician assistant’s Schedule II drug order, and, instead, require
that the supervising physician and surgeon use one of 2 described
mechanisms to ensure adequate supervision of the administration,
provision, or issuance by a physician assistant of a drug order to a patient
for Schedule II controlled substances.

The California Constitution requires the state to reimburse local
agencies and school districts for certain costs mandated by the state.
Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act
for a specified reason.

State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 3501 of the Business and Professions
Code is amended to read:
3501. (a) As used in this chapter:
(1) “Board” means the Physician Assistant Board.
(2) “Approved program” means a program for the education of
physician assistants that has been formally approved by the board.
(3) "Trainee" means a person who is currently enrolled in an approved program.

(4) "Physician assistant" means a person who meets the requirements of this chapter and is licensed by the board.

(5) "Supervising physician" or "supervising physician and surgeon" means a physician and surgeon licensed by the Medical Board of California or by the Osteopathic Medical Board of California who supervises one or more physician assistants, who possesses a current valid license to practice medicine, and who is not currently on disciplinary probation for improper use of a physician assistant.

(6) "Supervision" means that a licensed physician and surgeon oversees the activities of, and accepts responsibility for, the medical services rendered by a physician assistant.

(7) "Regulations" means the rules and regulations as set forth in Chapter 13.8 (commencing with Section 1399.500) of Title 16 of the California Code of Regulations.

(8) "Routine visual screening" means uninvasive nonpharmacological simple testing for visual acuity, visual field defects, color blindness, and depth perception.

(9) "Program manager" means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

(10) "Delegation of services agreement" means the writing that delegates to a physician assistant from a supervising physician the medical services the physician assistant is authorized to perform consistent with subdivision (a) of Section 1399.540 of Title 16 of the California Code of Regulations.

(11) "Other specified medical services" means tests or examinations performed or ordered by a physician assistant practicing in compliance with this chapter or regulations of the Medical Board of California promulgated under this chapter.

(12) "Medical records review meeting" means a meeting between the supervising physician and the physician assistant during which a sample of medical records are reviewed to ensure adequate supervision of the physician assistant functioning under protocols. The number of medical records and the specific issues to be reviewed shall be established in the
delegation of services agreement. Medical records review meetings may occur in person or by electronic communication.

(b) A physician assistant acts as an agent of the supervising physician when performing any activity authorized by this chapter or regulations adopted under this chapter.

SEC. 2. Section 3502 of the Business and Professions Code is amended to read:

3502. (a) Notwithstanding any other law, a physician assistant may perform those medical services as set forth by the regulations adopted under this chapter when the services are rendered under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting that supervision or prohibiting the employment of a physician assistant. The medical record, for each episode of care for a patient, shall identify the physician and surgeon who is responsible for the supervision of the physician assistant. When a physician assistant transmits an oral order, he or she shall also identify the name of the supervising physician and surgeon responsible for the patient.

(b) (1) Notwithstanding any other law, a physician assistant performing medical services under the supervision of a physician and surgeon may assist a doctor of podiatric medicine who is a partner, shareholder, or employee in the same medical group as the supervising physician and surgeon. A physician assistant who assists a doctor of podiatric medicine pursuant to this subdivision shall do so only according to patient-specific orders from the supervising physician and surgeon.

(2) The supervising physician and surgeon shall be physically available to the physician assistant for consultation when that assistance is rendered. A physician assistant assisting a doctor of podiatric medicine shall be limited to performing those duties included within the scope of practice of a doctor of podiatric medicine.

(c) (1) A physician assistant and his or her supervising physician and surgeon shall establish written guidelines for the adequate supervision of the physician assistant. This requirement may be satisfied by the supervising physician and surgeon adopting protocols for some or all of the tasks performed by the physician assistant. The protocols adopted pursuant to this subdivision shall comply with the following requirements:
(A) A protocol governing diagnosis and management shall, at a minimum, include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be provided to the patient.

(B) A protocol governing procedures shall set forth the information to be provided to the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the followup care.

(C) Protocols shall be developed by the supervising physician and surgeon or adopted from, or referenced to, texts or other sources.

(D) Protocols shall be signed and dated by the supervising physician and surgeon and the physician assistant.

(2) (A) The supervising physician and surgeon shall use one or more of the following mechanisms to ensure adequate supervision of the physician assistant functioning under the protocols:

(i) The supervising physician and surgeon shall review, countersign, and date a sample consisting of, at a minimum, 5 percent of the medical records of patients treated by the physician assistant functioning under the protocols within 30 days of the date of treatment by the physician assistant.

(ii) The supervising physician and surgeon and physician assistant shall conduct at least 10 times annually a medical records review meeting, which may occur in person or by electronic communication: meeting, at least once a month during at least 10 months of the year. During any month in which a medical records review meeting occurs, the supervising physician and surgeon and physician assistant shall review an aggregate of at least 10 medical records of patients treated by the physician assistant functioning under protocols. Documentation of medical records reviewed during the month shall be jointly signed and dated by the supervising physician and surgeon and the physician assistant.

(iii) The supervising physician and surgeon shall supervise the care provided by the physician assistant through a review of those cases or patients deemed appropriate cases involving treatment by the physician assistant functioning under protocols adopted by the supervising physician and surgeon. The review methods used shall be identified in the delegation of services agreement, and
review may occur in person or by electronic communication.

agreement and shall include no less than an aggregate of 10 cases
per month for at least 10 months of the year. Documentation of
the cases reviewed during the month shall be jointly signed and
dated by the supervising physician and surgeon and the physician
assistant.

(B) In complying with subparagraph (A), the supervising
physician and surgeon shall select for review those cases that by
diagnosis, problem, treatment, or procedure represent, in his or
her judgment, the most significant risk to the patient.

(3) Notwithstanding any other law, the Medical Board of
California or the board may establish other alternative mechanisms
for the adequate supervision of the physician assistant.

(d) No medical services may be performed under this chapter
in any of the following areas:

(1) The determination of the refractive states of the human eye,
or the fitting or adaptation of lenses or frames for the aid thereof.

(2) The prescribing or directing the use of, or using, any optical
device in connection with ocular exercises, visual training, or
orthoptics.

(3) The prescribing of contact lenses for, or the fitting or
adaptation of contact lenses to, the human eye.

(4) The practice of dentistry or dental hygiene or the work of a
dental auxiliary as defined in Chapter 4 (commencing with Section
1600).

(e) This section shall not be construed in a manner that shall
preclude the performance of routine visual screening as defined
in Section 3501.

(f) Compliance by a physician assistant and supervising
physician and surgeon with this section shall be deemed
compliance with Section 1399.546 of Title 16 of the California
Code of Regulations.

SEC. 3. Section 3502.1 of the Business and Professions Code
is amended to read:

3502.1. (a) In addition to the services authorized in the
regulations adopted by the Medical Board of California, and except
as prohibited by Section 3502, while under the supervision of a
licensed physician and surgeon or physicians and surgeons
authorized by law to supervise a physician assistant, a physician
assistant may administer or provide medication to a patient, or
transmit orally, or in writing on a patient’s record or in a drug
order, an order to a person who may lawfully furnish the
medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority
to issue a drug order to a physician assistant may limit this authority
by specifying the manner in which the physician assistant may
issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the
authority to issue a drug order to a physician assistant shall first
prepare and adopt, or adopt, a written, practice specific, formulary
and protocols that specify all criteria for the use of a particular
drug or device, and any contraindications for the selection.
Protocols for Schedule II controlled substances shall address the
diagnosis of illness, injury, or condition for which the Schedule II
controlled substance is being administered, provided, or issued.
The drugs listed in the protocols shall constitute the formulary and
shall include only drugs that are appropriate for use in the type of
practice engaged in by the supervising physician and surgeon.
When issuing a drug order, the physician assistant is acting on
behalf of and as an agent for a supervising physician and surgeon.

(b) “Drug order,” for purposes of this section, means an order
for medication that is dispensed to or for a patient, issued and
signed by a physician assistant acting as an individual practitioner
within the meaning of Section 1306.02 of Title 21 of the Code of
Federal Regulations. Notwithstanding any other provision of law,
(1) a drug order issued pursuant to this section shall be treated in
the same manner as a prescription or order of the supervising
physician, (2) all references to “prescription” in this code and the
Health and Safety Code shall include drug orders issued by
physician assistants pursuant to authority granted by their
supervising physicians and surgeons, and (3) the signature of a
physician assistant on a drug order shall be deemed to be the
signature of a prescriber for purposes of this code and the Health
and Safety Code.

(c) A drug order for any patient cared for by the physician
assistant that is issued by the physician assistant shall either be
based on the protocols described in subdivision (a) or shall be
approved by the supervising physician and surgeon before it is
filled or carried out.
(1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.

(2) A physician assistant shall not administer, provide, or issue a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for that particular patient unless the physician assistant has completed an education course that covers controlled substances and that meets standards, including pharmacological content, approved by the board. The education course shall be provided either by an accredited continuing education provider or by an approved physician assistant training program. If the physician assistant will administer, provide, or issue a drug order for Schedule II controlled substances, the course shall contain a minimum of three hours exclusively on Schedule II controlled substances. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established by the board prior to the physician assistant’s use of a registration number issued by the United States Drug Enforcement Administration to the physician assistant to administer, provide, or issue a drug order to a patient for a controlled substance without advance approval by a supervising physician and surgeon for that particular patient.

(3) Any drug order issued by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon’s practice.

(d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient’s medical record in a health facility or medical practice, shall contain the printed name, address, and telephone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug
order in a patient's medical record in a health facility or a medical
practice, shall include the federal controlled substances registration
number of the physician assistant and shall otherwise comply with
Section 11162.1 of the Health and Safety Code. Except as
otherwise required for written drug orders for controlled substances
under Section 11162.1 of the Health and Safety Code, the
requirements of this subdivision may be met through stamping or
otherwise imprinting on the supervising physician and surgeon's
prescription blank to show the name, license number, and if
applicable, the federal controlled substances registration number
of the physician assistant, and shall be signed by the physician
assistant. When using a drug order, the physician assistant is acting
on behalf of and as the agent of a supervising physician and
surgeon.

(e) The supervising physician and surgeon shall use either of
the following mechanisms to ensure adequate supervision of the
administration, provision, or issuance by a physician assistant of
a drug order to a patient for Schedule II controlled substances:

(1) The medical record of any patient cared for by a physician
assistant for whom the physician assistant's Schedule II drug order
has been issued or carried out shall be reviewed, countersigned,
and dated by a supervising physician and surgeon within seven
days.

(2) If the physician assistant has documentation evidencing the
successful completion of an education course that covers controlled
substances, and that controlled substance education course (A)
meets the standards, including pharmacological content, approved
by the board, established in Sections 1399.610 and 1399.612 of
Title 16 of the California Code of Regulations, and (B) is provided
either by an accredited continuing education provider or by an
approved physician assistant training program, and (C) satisfies
Sections 1399.610 and 1399.612 of Title 16 of the California Code
of Regulations, the supervising physician and surgeon shall review,
countersign, and date, within seven days, a sample consisting of
the medical records of at least 20 percent of the patients cared for
by the physician assistant for whom the physician assistant's
Schedule II drug order has been issued or carried out. Completion
of the requirements set forth in this paragraph shall be verified and
documented in the manner established in Section 1399.612 of Title
16 of the California Code of Regulations. Physician assistants who
have a certificate of completion of the course described in paragraph (2) of subdivision (c) shall be deemed to have met the education course requirement of this subdivision.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The board shall consult with the Medical Board of California and report during its sunset review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
Legislation of Interest to the Physician Assistant Board
SB 337 (Pavely)

The California Academy of Physician Assistants (CAPA) has provided the following materials for agenda item 3, including:

- Latest proposed amendments to BPC 3502 (2)(A) (i), (ii), and (iii)
- Assembly Committee on Business and Professions bill analysis: June 23, 2015
- CAPA SB 337 informational bulletin
- SB 337 Fact Sheet (Author: Senator Fran Pavely)

Teresa Anderson of CAPA has stated that the proposed amendments to BPC 3502(2)(A) (i), (ii), and (iii) have been approved by Senator Pavely’s office. CAPA indicated to us that they have started the legislative process to amend the bill. The bill will not be amended until it goes to the Assembly Floor.
(2) (A) The supervising physician and surgeon shall use one or more of the following mechanisms to ensure adequate supervision of the physician assistant functioning under the protocols:

(i) The supervising physician and surgeon shall review, countersign, and date a sample consisting of, at a minimum, 5 percent of the medical records of patients treated by the physician assistant functioning under the protocols within 30 days of the date of treatment by the physician assistant.

(ii) The supervising physician and surgeon and physician assistant shall conduct a medical records review meeting, at least once a month during at least 10 months of the year. During any month in which a medical records review meeting occurs, the supervising physician and surgeon and physician assistant shall review an aggregate sample of at least 10 medical records of patients treated by the physician assistant functioning under protocols. Documentation of medical records reviewed during the month shall be jointly signed and dated by the supervising physician and surgeon and the physician assistant.

(iii) The supervising physician and surgeon shall use a combination of the co-signature and medical records review meeting mechanisms. The documentation required for such reviews shall consist of an aggregate sample of at least 10 medical records per month and such reviews shall occur during at least 10 months of the year.
Date of Hearing: June 23, 2015

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Susan Bonilla, Chair
SB 337(Pavley) – As Amended June 16, 2015

SENATE VOTE: 38-0

SUBJECT: Physician assistants.

SUMMARY: Authorizes a physician supervising a physician assistant (PA) to use two additional mechanisms for the general supervision of a PA, authorizes a physician to use one additional mechanism for the supervision of a PA that administers a Schedule II controlled substance, and requires a PA's patient medical records to identify the PA's supervising physician.

EXISTING LAW:

1) Establishes the Physician Assistant Board (PAB) within the jurisdiction of the Medical Board of California (MBC) to license and regulate PAs. (Business and Professions Code (BPC) § 3504)

2) Requires a PA and the supervising physician to establish written guidelines for the adequate supervision of the PA, and the requirement may be satisfied by the supervising physician adopting protocols for some or all of the tasks performed by the PA. (BPC § 3502 (c)(1))

3) Requires a supervising physician to be available in person or by electronic communication at all times when the PA is caring for patients. (Title 16, California Code of Regulations (CCR) § 1399.545 (a))

4) Requires a supervising physician to delegate to a PA only the tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition, and requires the supervising physician to observe or review evidence of the PA's performance of all tasks and procedures to be delegated to the PA until the physician is assured of the PA's competency. (16 CCR § 1399.545 (b)(c))

5) Requires a supervising physician to review, countersign, and date a sample consisting of, at a minimum, five percent of the medical records of patients treated by the PA within 30 days of the date of treatment. Requires the supervising physician to select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgement, the most significant risk to the patient. (BPC § 3502 (c)(2))

6) Authorizes the MBC or the PAB to establish other alternative mechanisms for the adequate supervision of the PA. (BPC § 3502 (c)(3))

7) Requires a supervising physician who delegates the authority to issue a drug order to a PA to first prepare and adopt a formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. Protocols for Schedule II controlled substances must address the diagnosis of illness, injury, or condition for which...
the Schedule II controlled substance is being administered, provided, or issued. (BPC § 3502.1(a)(2))

8) Requires a supervising physician to review and countersign within seven days the record of any patient cared for by a PA for whom the PA’s Schedule II drug order has been issued or carried out. (BPC § 3502.1 (e))

9) Allows a PA to administer Schedule II, III, IV and V drug orders without advance approval from a supervising physician if the PA has completed an education course that covers controlled substances and that meets standards, including pharmacological content, approved by the PAB. The education course must be provided either by an accredited continuing education provider or by an approved PA training program. For Schedule II controlled substances, the course must contain a minimum of three hours exclusively on Schedule II controlled substances. (BPC § 3502.1 (c)(2))

10) Requires PAs who are authorized by their supervising physician to issue drug orders for controlled substances to register with the United States Drug Enforcement Administration (DEA). (BPC § 3502.1 (f))

THIS BILL:

1) Revises the definition of “medical records review meeting” to mean a meeting between the supervising physician and the PA during which medical records are reviewed to ensure adequate supervision of the PA functioning under protocols.

2) Authorizes the supervising physician and PA to hold medical records review meetings in person or by electronic communication.

3) Requires the medical record, for each episode of care for a patient, to identify the physician who is responsible for the supervision of the PA.

4) Authorizes a physician to choose from two additional mechanisms to supervise a PA, making a total of three mechanisms:

   a) Conduct a medical records review meeting at least once a month during at least 10 months of the year—any month in which a medical records review meeting occurs, the supervising physician and PA must review an aggregate of at least 10 medical records of patients treated by the PA. Documentation of medical records reviewed during the month must be jointly signed and dated by the supervising physician and the PA.

   b) Develop review methods for the review of cases involving treatment by the PA. The review methods must be identified in the delegation of services agreement and include at least an aggregate of 10 cases per month for at least 10 months of the year. Documentation of the cases reviewed during the month must be jointly signed and dated by the physician and PA.

5) States that, in complying with the supervision requirements above (number 4), the physician must select for review those cases that by diagnosis, problem treatment, or procedure represent, in the physician’s judgment, the most significant risk to the patient.
6) States that compliance with BPC § 3502 (numbers 3-5 above) will be also considered compliance with § 1399.546 of Title 16 of the California Code of Regulations.

7) Authorizes a physician to use an additional mechanism for the supervision of a PA that prescribes a Schedule II controlled substance. The physician may review, countersign, and date, within seven days, a sample consisting of the medical records of at least 20 percent of the patients with the PA’s Schedule II prescriptions if:

a) The PA has:
   i) Completed a controlled substances education course that meets the standards established in the PAB’s regulations and is provided either by an accredited continuing education provider or by an approved physician assistant training program; or,
   ii) The PA has a certificate of completion of the course described BPC § 3502.1(c)(2);

b) The supervision is verified and documented in the manner established by the PAB’s regulations.

8) Makes other minor technical and clarifying changes.

FISCAL EFFECT: According to the Senate Appropriations Committee, pursuant to Senate Rule 28.8, this bill will result in negligible state costs.

COMMENTS:

Purpose. This bill is sponsored by the California Academy of Physician Assistants. According to the author, “[This bill] increases options for the physician/PA team to document supervision. The options included in the bill will strengthen the team-based approach by encouraging more active discussion during the records review.

The Patient Protection and Affordable Care Act has resulted in millions of additional people seeking health care services in California. This increase has created an even greater need for high quality, efficient team-based care across all medical settings.

This is especially true for the practice of physician assistants, who are authorized to provide physician exams, diagnose and treat illness, and prescribe medication, under the supervision of a physician. [This bill] recognizes the growing changes in medical practice settings and the use of electronic medical records to update methods for documentation of the supervision of PAs and encourages more interactive review of patient cases.”

Background. According to the PAB, a PA is a licensed health care professional, trained to provide patient evaluation, education, and health care services. A PA works with a physician to provide medical care and guidance needed by a patient.

In order to become a PA, an applicant must attend a specialized medical training program associated with a medical school that includes classroom studies and clinical experience. Upon graduation from the program, an academic degree or certificate is awarded. Many PAs already
have two or four year academic degrees before entering a PA training program. Most PA 
training programs require prior health care experience.

While a licensed PA is authorized to perform many of the same health care services as a 
physician, the services the PA may provide are limited to the services expressly authorized by 
the PA’s supervising physician. The physician’s written authorization is known as a delegation 
of services agreement. In the agreement, the physician is allowed to authorize only the services 
that the physician determines the PA competent to perform, consistent with the PA’s education, 
training, and experience.

As of June 2013, there were about 9,000 active PA licenses in California.

General Supervision Requirements. Existing law requires each PA to be supervised by at least 
one physician. The physician may supervise the PA either when both are at the same location or 
by telephone. Further, the physician must be physically or electronically available to the PA at 
the time of treatment.

The PA and the supervising physician must also establish written guidelines for the adequate 
supervision of the PA. The requirement may be satisfied by adopting protocols for some or all of 
the tasks performed by the PA.

In addition, the physician is responsible for following each patient’s progress and must review, 
countersign, and date a sample of at least five percent of a PA’s patient medical records within 
30 days of treatment. The physician decides to review cases that represent the most significant 
risk to the patient.

According to the author, the current five percent requirement does not accommodate all care 
delivery models, which can lead to less access to care and supervision issues. This bill seeks to 
add two additional mechanisms to allow a supervising physician more options to adequately 
supervise a PA:

1) Allow the physician to conduct a medical records review meeting at least once a month 
during at least 10 months of the year. In the months in which a medical records review 
meeting occurs, the physician and PA must review at least 10 of the PA’s patient medical 
records. This option would allow a physician to spread the meetings out over the year rather 
than as the treatments occur.

2) Allow the physician to develop the method for reviewing cases. The review methods must 
be identified in the delegation of services agreement and include at least an aggregate of 10 
cases per month for at least 10 months of the year. This option would allow the physician to 
combine several months of review, for instance if the physician wants to physically review 
the records but is only in the area six months out of the year.

Supervision of Controlled Substances. Under the United States Controlled Substances Act, the 
DEA classifies drugs into five categories (schedules), depending upon the drug’s acceptable 
medical use and the drug’s abuse or dependency potential. As the schedule number decreases, 
the higher the concern for potential abuse—Schedule V drugs present the least potential for 
abuse, while Schedule II drugs are considered to have a high potential. Schedule I drugs 
typically have no accepted medical purpose.
Existing law allows a supervising physician to authorize a PA to prescribe drugs classified as Schedule II, III, IV and V if:

1) The physician develops practice specific, written protocols and formularies. The protocols for Schedule II controlled substances must address diagnosis of illness, injury, or condition for which the drug is being prescribed;

2) The PA registers with the DEA; and,

3) The PA obtains advanced approval from the physician.

In addition, a PA may prescribe controlled substances without advanced approval by the supervising physician if the PA has completed a controlled substance education course that meets standards approved by the PAB. For Schedule II controlled substances, the course must spend at least three hours exclusively on Schedule II controlled substances.

There is also an additional supervision requirement for Schedule II controlled substances—the physician must reviews, countersign, and date the medical record of all the PA’s patients within seven days of prescribing the drug. Schedule III and IV drugs do not have a countersigning requirement, but the physician is still required to review the medical records of the PA’s patients overall. The PAB is also required to consult with the Medical Board of California and report during sunset review the impacts of the exemption. The PAB is up for sunset review in 2016.

According to the author, the 100% countersigning requirement is also prohibitive to many new care delivery models. Because existing law allows a physician to provide supervision electronically, PA-lead clinics may be unable to provide Schedule II drugs if the physician must be physically available to countersign the medical records within seven days for every prescription. Further, there are still the general supervision requirements, which may create a duplicative or overlapping signing requirement for Schedule II drugs.

The Reclassification of HCP to Schedule II. In August of 2014, the DEA published a final rule, effective October 6, 2014, following recommendations from the U.S. Food and Drug Administration (FDA) to reclassify hydrocodone combination products (HCP) from a Schedule III controlled substance to a Schedule II. HCP products, such as Vicodin, are popular alternatives to Oxycodone for pain management (due to risk of addiction and side effects). According to the author, “the new ruling restricts the ability of a practice to fully utilize the PAs they employee as there is no other profession with prescribing privileges that has that level of mandate for documentation.”

Other States. The Schedule II countersigning requirements vary from state-to-state. Some states have no countersigning requirement and others do not permit PAs to administer Schedule II drugs at all.

Prior Related Legislation. SB 1069 (Pavley), Chapter 512, Statutes of 2010, authorized a PA, pursuant to a delegation of services agreement, to order durable medical equipment, certify unemployment insurance disability, and for individuals receiving home health services or personal care services, after consultation with the supervising physician, approve, sign, modify, or add to a plan of treatment or plan of care. The bill also authorized PAs to conduct specified medical examinations and sign corresponding medical certificates for various individuals.
AB 3 (Bass), Chapter 376, Statutes of 2007, created the "California Team Practice Improvement Act" which deleted the prohibition on the authority of a PA to issue a drug order for specified classes of controlled substances if the PA has completed a specified education course, required a PA and his or her supervising physician to establish written supervisory guidelines and protocols, increased to four the number of PAs a physician may supervise, and specified that services provided by a PA are included as covered benefits under the Medi-Cal program.

AB 2626 (Plescia) Chapter 452, Statutes of 2004, removed the requirement for the supervising physician to review, co-sign and date each prescription written by a PA and limited the co-signature requirement to each Schedule II drug order written by a PA.

ARGUMENTS IN SUPPORT:

The California Academy of Physician Assistants (sponsor) writes in support, "Established over 30 years ago, existing law stipulates supervision criteria between a supervising physician and surgeon and the [PA]. It narrowly defines documentation of this required supervision in the form of the supervising physician co-signature on the medical record and prescriptions. [This bill] increases the options for documenting supervision between a supervising physician and PA would allow for flexibility at the practice level to reflect current models of team-based care. This bill will allow physicians and PA’s to spend more time with patients.”

ARGUMENTS IN OPPOSITION:

The Medical Board of California writes in opposition, “[the MBC] recognizes that the intent of this bill is to provide flexibility and allow for a more team-based approach in PA supervision, which the [MBC] believes is a laudable goal. The recent amendments addressed concerns raised by the [MBC]…. However, the [MBC] still has concerns related to the reduced physician review of Schedule II drug orders from 100 percent to 20 percent, as this is a significant reduction of supervising physician review for types of opioid medications that are prevalent for abuse.”

REGISTERED SUPPORT:

California Academy of Physician Assistance (sponsor)
CAPG, the Voice of Accountable Physician Groups
Pacific Pain Medicine Consultants
Planned Parenthood
253 PAs
56 M.D.s and D.O.s

REGISTERED OPPOSITION:

Medical Board of California
California Pharmacists Association

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INTRODUCTION

The California Academy of Physician Assistants ("CAPA") is a nonprofit professional association that represents the physician assistant ("PA") profession in California. CAPA is a constituent chapter of the American Academy of Physician Assistants. CAPA's goals include expanding access to care by promoting regulatory and legislative changes that will enhance the ability of PAs to provide safe, cost-effective medical care to the residents of California. CAPA is committed to team practice between physicians and PAs, and supports the concept of physician supervision as a means of assuring patient safety and quality health care.

PAs are licensed health professionals who practice medicine as members of a physician-led team, delivering a broad range of medical and surgical services to diverse populations in rural, urban and suburban settings. As part of their comprehensive responsibilities, PAs are authorized, under the supervision of a physician, to prescribe medication, conduct physical exams, diagnose and treat illnesses, order and interpret tests, counsel on preventive health care, perform delegated procedures, and assist in surgery.

SUPERVISION REQUIREMENTS UNDER CURRENT LAW

Under existing law, a PA's supervising physician must determine through observation or other evidence that the PA is competent to perform those services which the supervising physician may delegate to the PA. The PA Practice Act additionally requires that the supervising physician be available electronically at all times while the PA is providing services and that written back-up procedures are documented. The supervising physician is ultimately responsible and legally liable for the acts or omissions of the PA.

In addition to the above supervision requirements, under existing law, the supervising physician must establish written guidelines which must include one of the following: (1) examination of the patient by the supervising physician the same day that care is given by the PA; (2) co-signature and dating by the supervising physician of the medical records of all patients seen by the PA within 30 days; or (3) the use of protocols by the PA, accompanied by the co-signing by the physician of 5% of the medical records of the patients seen by the PA (or 100% of the records when a Schedule II Controlled Substance has been prescribed or administered to the patient.) In actual practice, most supervising physicians and PAs utilize protocols as their primary means of ensuring supervision.

The current 5% co-signature requirement reflects a change in the law made by the Legislature in 2007, when the PA Practice Act was amended to reduce the percentage of required co-signatures from 10% to 5%. Notably, there have been no reports whatsoever of any adverse events as a result of this change. On the other hand, however, it is widely believed that supervising physicians are able to devote more time to patient care as a result of the reduced administrative burdens resulting from this change. There is every reason to expect that the removal of a co-signature requirement would further enhance access to care by permitting PAs and their
Reasons Why the Co-signature Requirement Should Be Eliminated

The co-signature requirement flies in the face of two key federal laws designed to increase and enhance access to care. It is also contrary to sound health policy, as a number of studies have verified.

1. The Co-signature Requirement Conflicts with the HITECH Act.

First, the Health Information Technology for Clinical and Economic and Clinical Health Act ("HITECH Act") was passed by Congress in 2010 with the goal of increasing and streamlining the use of electronic health records ("EHRs"). To summarize, HITECH requires physicians and hospitals to adopt the meaningful use of EHRs. Covered providers who do so are rewarded with additional funding from Medicare and Medi-Cal, while providers who fail to do so are punished through a reduction in their Medicare and Medi-Cal payments.

Unfortunately, many of the more than 750 federally certified EHR systems developed in response to the HITECH Act do a poor job of accommodating the California specific requirement for co-signatures on the charts of patients who have been seen by PAs. The co-signature requirement for PAs was designed based on the use of paper medical records. CAPA has validated these concerns through a survey of its members conducted in 2009, after a number of issues arose regarding PAs' and supervising physician's inability to electronically co-sign EHRs. The survey results indicated that 35% of respondents were using some form of EHRs at the time, and that 21% reported that their EHR system would not allow PAs to sign the medical record electronically or permit the supervising physician to co-sign the record.

2. The Co-signature Requirement Also Conflicts with the Patient Protection and Affordable Care Act

The second key law implicated by the co-signature requirement is the Patient Protection and Affordable Care Act ("ACA"). As a result of the ACA, California has reported enrolling 3.4 million new-insured individuals, including 1.3 million through California Covered plans and 1.9 million through Medi-Cal. Other states have seen similar expansions. To address the issues raised by this huge national influx of insured patients, the National Governors Association ("NGA") recently published an issues brief specific to PA practice which suggests that states evaluate their laws and regulations governing PA practice to ensure they are sufficiently flexible to allow PAs to practice to the full extent of their training. The NGA brief reports that 25 states have no minimum requirement related to co-signatures and suggests that decisions regarding co-signature and other supervisory issues be made at the practice level.

Indeed, the increased demand for health care services generated by the ACA has raised a chorus of voices advocating for more flexibility in delivering team-based health care services. For example, a Joint Statement published by the American Academy of Family Physicians and the American Academy of Physician Assistants in 2011 acknowledges the critical role of the physician/PA team in improving access to care and suggests that there be "flexibility in federal and state regulation so that each medical practice determines within the defined spectrum of appropriate clinical roles within the medical team ... and supervision processes enabling each clinician to work to the fullest extent of his or her education and expertise.” Though the
guidelines specify that the physician must regularly review the quality of medical services rendered by the PA, they do not specify a minimum chart review requirement or a specific method of supervision. However, they do recommend that the physician consider the scope of duties that have been delegated, and the experience and patient load of the PA when defining supervision requirements.

Similarly, the American Medical Association (AMA) recently adopted a policy promoting "flexibility to develop practice designs based on physician needs, the population they serve, relevant state laws and protections from the burdens that would come from a one-size-fits-all approach." The American Academy of Physician Assistants in 2013 surveyed PAs nationally and found a variety of supervising methods were implemented, including face-to-face, video conferencing, telephone, email, and other methodologies.

**CONCLUSION**

For the foregoing reasons, the requirement for the supervising physician to co-sign 5% of the charts for patients treated using protocols and 100% of the charts of patients who receive Schedule II controlled substances is unnecessary and counterproductive, and should therefore be eliminated. Co-signature requirements were established for use with a paper medical record, but with most PAs using EHRs which are often not well designed for co-signatures, there is no reason to require them. Moreover, supervising physicians are quite capable of monitoring the treatment provided by their PAs without the need to co-sign an artificial minimum percentage of charts. The reduction of the percentage of charts from 10% to 5% in 2008, without any adverse impact whatsoever on patient care, provides a solid precedent for this additional change.

Finally, it is important to note that nothing in our proposal would preclude a supervising physician from continuing to review any percentage of patient charts he or she deems appropriate (up to 100%), based on the PA’s experience and training, as well as the acuity of the patients involved in other relevant factors.
THE PROBLEM
The Patient Protection and Affordable Care Act has resulted in millions of additional people seeking health care services in California. This increase has created an even greater need for high quality, efficient team-based care across all medical settings. This is especially true for the practice of physician assistants, who are authorized to provide physician exams, diagnose and treat illness, and prescribe medication, under the supervision of a physician.

Established over 30 years ago, existing law stipulates the supervision criteria between a supervising physician and surgeon and the Physician Assistant (PA). It narrowly defines documentation of this required supervision in the form of the supervising physician co-signature on the medical record.

Existing law also authorizes either in-person or electronic supervision of a Physician Assistant. Given this authorization, PAs are well suited to expand the access of care for the care team and may serve as the lead clinician on-site for the delivery of care. While established criteria for documenting supervision works well in some settings, it does not reflect or allow for documentation of supervision in many current models of team-based care.

In particular, flexibility is needed in documenting the large number of general Physician Assistant medical visits, as well as documenting supervision related to writing orders for Schedule II medications. Current law requires a supervising physician to co-sign 100% of the medical charts of patients prescribed Schedule II medications by a PA within 7 days.

In October 2014, hydrocodone combination products (HCPs) were re-scheduled from a Schedule III medication to a Schedule II medication, thus significantly increasing administrative responsibilities related to documentation in various practice types.

THE SOLUTION
SB 337 recognizes the need to streamline patient care performed by physician assistants under the supervision of physicians. The bill provides greater flexibility to medical practices by offering physicians several options to ensure adequate supervision of Physician Assistant medical visits.

Specifically, SB 337 increases options for the physician/PA team to document supervision, pertaining to two types of medical appointments:

- For general PA medical visits, the bill allows the following: 1) the continuation of existing law which requires physicians to co-sign five percent of medical visits, 2) medical record review meetings at least 10 times annually, or 3) a combination of review and documentation methods established by the supervising physician appropriate for the practice setting.

- For PA medical visits pertaining to prescriptions for Schedule II medications, the bill allows either the continuation of existing law which requires co-signatures on all medical charts, or 2) requires the supervising physician to co-sign a sample of 20% of the medical records within 7 days IF the PA has successfully completed a controlled substance education course that meets specified requirements under law.
It is important to note that a supervising physician may review any percentage of patient charts he or she deems appropriate (up to 100%), based on the PA’s experience and training, as well as the acuity of the patients involved in other relevant factors. All supervision documentation requirements will be recorded in the delegation of services agreement, which is located at each site the PA provides services.

**BACKGROUND**

There are approximately 10,000 PAs practicing across almost every discipline of medicine in California. PAs are licensed health professionals who practice medicine as members of a physician-led team, delivering a broad range of medical and surgical services to diverse populations in rural, urban and suburban settings. As part of their comprehensive responsibilities, PAs are authorized, under the supervision of a physician, to prescribe medication (write drug orders), conduct physical exams, diagnose and treat illnesses, order and interpret tests, counsel on preventive health care, perform delegated procedures and assist in surgery.

PAs are increasingly acquiring administrative roles and responsibilities as well. The delegation of services agreement (DSA) is the legal document that is for the mutual benefit and protection of the patients, supervising physicians and their PAs as PA laws and regulations require the supervising physician to delegate in writing those medical services which the PA is authorized to perform. Further, the medical services that are delegated must be those that are usual and customary to the physician’s practice.

Increasing the options for documenting supervision between a supervising physician and PA would allow for flexibility at the practice level and reflect current models of team-based care. As licensed health care Professionals, PAs practice medicine in team-based care and are delegated tasks, by the supervising physician, appropriate to their education, experience and training. The supervising physician has the ultimate responsibility for the patient and therefore should be able to choose the method of documenting supervision that best suits and reflects the unique needs of his or her practice.

**FEDERAL LAW AND OTHER STATES**

The laws and regulations pertaining to the documentation of supervision between a supervising physician and PA vary from state to state. A review of other state laws and regulations found 25 other states do not have a co-signature requirement.

**SPONSOR**

California Academy of Physician Assistants (CAPA)